# EXHIBIT 7

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE DIGITEK®
PRODUCTS LIABILITY LITIGATION

MDL NO. 1968

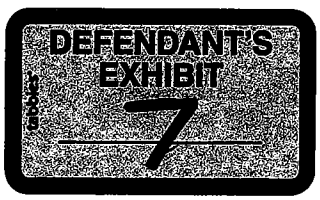
THIS DOCUMENT RELATES TO ALL CASES

**ANSWERS OF DEFENDANTS ACTAVIS INC., ACTAVIS TOTOWA LLC AND ACTAVIS ELIZABETH LLC TO PLAINTIFFS' FIRST SET OF INTERROGATORIES DIRECTED TO DEFENDANTS**

The properly served and represented Defendants Actavis Inc., Actavis Totowa LLC ("Actavis Totowa"), and Actavis Elizabeth LLC ("Actavis Elizabeth") (collectively, "Defendants") respond to Plaintiffs' First Set of Interrogatories ("Interrogatories") as follows:

**RESERVATION OF RIGHTS**

Defendants respond to Plaintiffs' Interrogatories to the best of their present knowledge, information and belief. These responses are subject to additional or different information that discovery or further investigation may disclose. Defendants do not waive or intend to waive, by reason of their responses, their rights to: (1) revise, amend, or supplement these responses; (2) object on any ground to the use of documents produced in these responses for any purpose, in whole or in part, in this or any other proceeding, action, or matter; (3) object on any grounds, at any time, to other discovery procedures or requests relating to the subject matter of the Interrogatories; and (4) object on the grounds of admissibility to any documents produced in relation to the responses to these Interrogatories.



## GENERAL OBJECTIONS

Defendants make the following General Objections, which are in addition to, and incorporated within, each of the specific responses set forth below:

1. Defendants object to Plaintiffs' instructions and definitions to the extent they attempt to enlarge the scope of permissible discovery under the Federal Rules of Civil Procedure, the Court's Pretrial Orders, and/or any other applicable rules.

2. Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way. As such, Defendants object to the Interrogatories, and the definitions and the instructions, to the extent they imply that Actavis Inc. and Actavis Elizabeth were involved with, or are primary custodians possessing any responsive documents relating to, the manufacture of Digitek®. Furthermore, Defendants assert that the responses set forth herein shall not be considered a waiver of any objection or an acknowledgement by Actavis Inc. and Actavis Elizabeth of involvement with, or possession of responsive documents relating to, the manufacture of Digitek®.

3. Defendants object to Plaintiffs' use of the term "Digitek" to the extent that it pertains to any product not manufactured, distributed, or marketed under the trade name Digitek®. Actavis Defendants further object to the extent that Plaintiffs' use of the term "Digitek" includes ingredients or products not manufactured, marketed, or distributed by a party to this lawsuit.

4. Defendants object to each Interrogatory to the extent it seeks information or documents protected from disclosure or production by the attorney-client privilege, the attorney work-product doctrine, joint defense or common interest privilege, accountant-client privilege, or by any other privilege or doctrine available under federal or state law, whether statutory,

regulatory, constitutional, or common law. Defendants further object to each Interrogatory to the extent it seeks the disclosure of information or documents protected by statutes, regulations, common law, and the Federal Rules of Civil Procedure that are either absolutely protected from production or which should be produced only pursuant to an appropriate protective order. Inadvertent disclosure of any such information shall not constitute a waiver of any privilege or any other ground for objecting to discovery with respect to such information, nor shall inadvertent disclosure waive the right of Defendants to object to the use of any such information in any proceeding. Defendants object to each Interrogatory to the extent it seeks any information or document relating to any drug other than Digitek®, the only product at issue in this litigation, which is not also reasonably related to the manufacture of Digitek®.

5. Defendants object to each Interrogatory to the extent it seeks any information or document relating to any drug other than Digitek®, the only product at issue in this litigation, which is not also reasonably related to the manufacture of Digitek®.

6. Defendants object to each Interrogatory to the extent it seeks discovery or production of confidential, trade secret, and/or proprietary information.

7. Defendants object to each Interrogatory to the extent it calls for the discovery of information already in Plaintiffs' possession, custody, or control, publicly available, or otherwise equally available to Plaintiffs, on grounds that such requests for information are unreasonably cumulative and duplicative, and that such information is obtainable from a source that is more convenient, less burdensome, and less expensive.

8. Defendants object to the extent any Interrogatory seeks information concerning a period of time prior or subsequent to the time period that any Plaintiff allegedly ingested

Digitek® on the grounds that such Interrogatory is overly broad, unduly burdensome, and seeks information that is not relevant to the subject matter of this action and is not reasonably calculated to lead to the discovery of admissible evidence.

9. Defendants object to each Interrogatory to the extent it is directed to any entity other than Actavis Totowa LLC, Actavis Inc., and Actavis Elizabeth LLC.

10. Defendants object to each Interrogatory to the extent it is vague, ambiguous, confusing, argumentative, overly broad, oppressive, and/or requires an unduly burdensome and unnecessarily expensive search for, and disclosure of, documents that are neither relevant to the claim or defense of any party in this action nor reasonably calculated to lead to the discovery of admissible evidence.

11. Defendants object to each Interrogatory to the extent it is duplicative and cumulative.

12. Defendants object to each Interrogatory to the extent it calls for the disclosure of information or the production of documents not within Defendants' possession, custody, or control.

Defendants respond to these Interrogatories without waiving the foregoing objections (which shall be deemed to apply to each and every Interrogatory), or any other objections set forth herein.

**INTERROGATORY NO. 1:**

Describe in detail, from start to finish, the manufacturing and sales procedures utilized for Digitek®, including, but not limited to, the manufacturing process, packaging, distribution and marketing of Digitek®. For each process described please list the following:

a) Describe in detail the role, if any, you played in the process;

b) Identify any other entity that played any role in the process; and

c) Describe in detail the role, if any, that any other entity played in the process.

**ANSWER:**

Defendants object to this Interrogatory because it is not limited to a relevant time frame, so it is overbroad and it is not reasonably calculated to lead to the discovery of admissible evidence. Responding to an interrogatory so overbroad in time and scope would be unduly burdensome for Defendants. This Interrogatory is also improper in that it seeks information about entities other than Defendants.

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way, and as such they join in the objections to this Interrogatory but not the substantive response.

Subject to the foregoing objections, Defendants respond as follows: All manufacturing operations occurred at the Actavis Totowa, Little Falls, New Jersey facility. The first general step of the manufacturing process was for employees to go to the room in which raw ingredients are stored. There, employees measure out the appropriate amounts of the raw materials that are called for by the formula for Digitek® which is contained in the ANDA. The appropriate raw materials were transported from the inventory area to a special area of the manufacturing facility, typically including Rooms 117, 119, and 120. Digitek® blending occurred in Room 117. There were generally three blenders in Room 117, along with their appropriate supporting equipment, a 10 cubic foot v-shaped blender, a 3 cubic foot portable blender, and a 50 cubic foot drum blender. The raw materials were first made into three pre-blends which were then combined into one final blend. During the blending process, employees took samples to assure blend

uniformity and, at the conclusion of the blending, weighed and measured the final blend in order to reconcile raw material usage. The blended Digitek® is a powder which, once blended, was placed into drums, which were placed onto a pallet, shrink wrapped, and labeled with the batch number.

After blending, the powdered blend was loaded through feed stations above Rooms 119 and 120. Actavis used 45 Station Stokes BB2 tablet presses – with ancillary equipment such as dedusters and metal detectors – for the compression of Digitek® powder into tablets. Press operators performed routine checks of tablets for appearance, thickness, weight, and hardness, and quality assurance employees made routine inspections for the same items. Once the tablets were compressed, finished goods were weighed in order to reconcile raw material usage with product output. The finished tablets, in buckets, were sealed, loaded onto pallets, shrink-wrapped and labeled with the batch number. They were then transferred to the Taft Road facility for packaging.

Once there, tablet buckets were moved down a conveyor system and serially emptied into feed hoppers which, in turn, moved down vibrating channel counters in order to fill bottles. The bottles were labeled at the labeling section of the machinery and placed into boxes. The finished packaged goods were counted and weighed in order to provide a final raw materials usage reconciliation. Before shipping, a designated amount of finished Digitek® tablets were chemically tested for dissolution, stability and dose uniformity. Once all laboratory testing was completed, the batch would be certified. Once that was done, the finished goods were ready for shipping to Mylan.

**INTERROGATORY NO. 2:**

For each strength of FDA approved Digitek® tablets, please state the FDA required:

a) Tablet Size;

b) Tablet weight; and

c) Amount of active ingredient.

**ANSWER:**

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way, and as such they join in the objections to this Interrogatory but not the substantive response.

Subject to the foregoing objections, Defendants respond to (a) and (b) as follows:

| PARAMETER | .125 mg (125 mc) | .250 mg (250 mc) |
|---|---|---|
| Target Weight (1)<br>Weight Range (1)<br>Target Weight (10)<br>Weight Range (10 Tablets) | 105 mg (0.105 g)<br>97 – 113 mg (0.097 - 0.113 g)<br>1.050 g<br>1.019 g – 1.082 g | 120 mg (0.120 g)<br>114 – 126 mg (0.114 -0.126 g)<br>1.20 g<br>1.176 g – 1.224 g |
| Thickness | 2.0 mm – 3.0 mm | 2.7 mm – 3.7 mm |
| Hardness | 1.0 – 6.0 kp | 2 – 8 kp |
| Appearance | Yellow, round; imprinted with "B145" on scored side | White, round; imprinted with "B146" on scored side |

c) The appropriate level of active ingredients required by the FDA is set forth in the United States Pharmacopeia (USP) which is publicly available.

**INTERROGATORY NO. 3:**

Describe in detail the training you provided your quality control unit responsible for Digitek® in the area of current good manufacturing practices including the person(s) that train the quality assurance employees and the frequency of such training.

**ANSWER:**

Defendants object to this Interrogatory because it is not limited to a relevant time frame, so it is overbroad and it is not reasonably calculated to lead to the discovery of admissible evidence. Responding to an Interrogatory so overbroad in time and scope would be unduly burdensome for Defendants.

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way, and as such they join in the objections to this Interrogatory but not the substantive response.

Subject to the foregoing objections, Defendants respond as follows: See response to Plaintiffs' Requests for Production of Documents #7.

**INTERROGATORY NO. 4:**

Describe and identify any automatic, mechanical, and electronic equipment or other types of equipment, including computers, or related systems that are used in the manufacture, processing, packing of Digitek® that controls or constrains strength of the drug and/or the amount of the drug's active ingredient that is used in the drug, and for each piece of equipment etc.:

a) describe how frequently it is calibrated, inspected, or checked;

b) identify and describe any problems with the piece of equipment that have occurred in the past five years; and

c) Identify and describe in detail any maintenance or repairs made to the piece of equipment in the past five years.

**ANSWER:**

Defendants object to this Interrogatory because it is not limited to a relevant time frame, so it is overbroad and it is not reasonably calculated to lead to the discovery of admissible evidence. Responding to an Interrogatory so overbroad in time and scope would be unduly burdensome for Defendants. This Interrogatory is also vague and confusing as written, and is particularly vague with respect to the undefined term "problems."

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way, and as such they join in the objections to this Interrogatory but not the substantive response.

Subject to the foregoing objections, Defendants respond as follows: The amount of active ingredient in the drug is specified in the ANDA for Digitek® and the raw ingredients for the drug are mixed during the blending phase of the manufacturing process to achieve compliance with the specifications set forth in the ANDA. Compliance with the ANDA specifications is tested at various phases of the manufacturing process including testing of the final blend prior to tablet compression and testing of pressed tablets during manufacturing and at the conclusion of tablet compression. See response to Interrogatory No. 1.

**INTERROGATORY NO. 5:**

Describe in detail each and every action you have undertaken in the last five years to verify that the strength, dose, quality and purity of Digitek® manufactured, packaged or distributed by you, including but not limited to the Recalled Digitek®, was consistent with the drug's labeling.

**ANSWER:**

Defendants object to this Interrogatory because it is overbroad and it is not reasonably calculated to lead to the discovery of admissible evidence. This Interrogatory is also vague and confusing as written, and is particularly vague with respect to the undefined term "each and every action you have undertaken." Responding to an Interrogatory so overbroad in time and scope would be unduly burdensome for Defendants.

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way, and as such they join in the objections to this Interrogatory but not the substantive response.

Subject to the foregoing objections, Defendants respond as follows: See response to Interrogatory Number 1. Raw materials received from suppliers were tested for compliance with their labeling. In addition, each batch of Digitek® underwent raw material usage reconciliation at various stages of the process, blend uniformity testing during the blending phase, and quality checks during tablet compression, all of which are designed to verify that the product is manufactured consistent with the drug's labeling. Specific details regarding these processes are set forth in detail in the records relating to the production of each batch of recalled Digitek®, which are being produced pursuant to PTO #16.

See, for example the following documents:

| Document Description | Batch No. | Production Bates Numbers |
|---|---|---|
| Raw Material Weighing/Blending Operations | 60371 | ACTAV000003996-000004012 |
| | 60372 | ACTAV000004245-000004261 |
| | 60373 | ACTAV000004974-000004990 |
| | 70924 | ACTAV000002120-000002136 |
| In-Process Blend Sampling Report | 60236 | ACTAV000003503-000003504 |
| | 60372 | ACTAV000004315-000004317 |
| | 60373 | ACTAV000005044-000005046 |
| | 70924 | ACTAV000002923-000002933 |
| Final Blend Sample Submission Report | 60371 | ACTAV000004185-000004186 |
| | 60372 | ACTAV000004428-000004429 |

| Document Description | Batch No. | Production Bates Numbers |
|---|---|---|
| | 60373 | ACTAV000005148-000005149 |
| Tablet Compression Operation Instructions | 60371 | ACTAV000004013-000004018 |
| | 60372 | ACTAV000004262-000004267 |
| | 60373 | ACTAV000004991-000004996 |
| | 70924 | ACTAV000002232-000002237 |
| Compression Data Sheet | 60371 | ACTAV000004019-000004023 |
| | 60372 | ACTAV000004268-000004272 |
| | 60373 | ACTAV000004997-000005001 |
| | 70924 | ACTAV000002238-000002242 |
| QA In-Process Compression Data Sheet | 60371 | ACTAV000004071-000004081 |
| | 60372 | ACTAV000004320-000004330 |
| | 60373 | ACTAV000005049-000005059 |
| | 70924 | ACTAV000002252-000002264 |

Defendants further refer Plaintiffs to documents similar to those identified above that can be found in each of the Digitek® batch records produced by Defendants.

**INTERROGATORY NO. 6:**

List and describe each complaint or notice of problems or adverse effects received by, or known to you, regarding the use of Digitek® in the past five years, including the date of the incident, the date you received notice, and a description of the incident including nature of the injury. (In response to this interrogatory, you may redact the names of the reports of adverse events in compliance with any applicable FDA regulation).

**ANSWER:**

Defendants object to this Interrogatory because it is overbroad and it is not reasonably calculated to lead to the discovery of admissible evidence. This Interrogatory is also vague and confusing as written, and is particularly vague with respect to the undefined term "notice of problems." Responding to an Interrogatory so overbroad in time and scope would be unduly burdensome for Defendants. Defendants also object on the grounds that the requested

information may infringe upon the privacy interests of patients or physicians or violate federal or state privacy laws or regulations, including 21 C.F.R. § 20.63(f).

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way, and as such they join in the objections to this Interrogatory but not the substantive response.

Subject to the foregoing objections, Defendants respond as follows: See Digitek® Annual Reports and Annual Product Reviews for 2003-2007, previously produced (ACTAV 000005279 - 000006568). See also documents that will be produced in response to Requests 24, 25, 26, and 27 of Plaintiffs' Request for Production of Documents.

**INTERROGATORY NO. 7:**

For each and every complaint or notice of problems or adverse effects identified above, please describe in detail the actions you took in response to receiving or gaining knowledge of the incident, including any investigation you performed of the incident or any report that you issued to the FDA. (This interrogatory asks what actions were taken after receipt of such complaint or notice of problem or adverse event, not just whether defendant made any changes as a result of such complaint or notice of problem or adverse event).

**ANSWER:**

Defendants object to this Interrogatory because it is overbroad and it is not reasonably calculated to lead to the discovery of admissible evidence. This Interrogatory is also vague and confusing as written, and is particularly vague with respect to the undefined term "notice of problems." Responding to an Interrogatory so overbroad in time and scope would be unduly burdensome for Defendants. Defendants also object on the grounds that the requested

information may infringe upon the privacy interests of patients or physicians or violate federal or state privacy laws or regulations, including 21 C.F.R. § 20.63(f).

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way, and as such they join in the objections to this Interrogatory but not the substantive response.

Subject to the foregoing objections, Defendants respond as follows: See Response to Interrogatory No. 6.

**INTERROGATORY NO. 8:**

Identify each instance in which the FDA alleged non-compliance relating to Digitek® [or any other drug] manufactured at the Little Falls facility in the last five years and give the following details:

a) each alleged non-compliant act stated by the FDA or one of its divisions;

b) the date(s) each such act was identified;

c) whether any citation, fine, warning or other penalty was issued for the non-compliant act; and

d) What, if any, action you took as a result of the FDA action.

**ANSWER:**

Defendants object to this Interrogatory because it is it is not limited to Digitek®, the only product at issue in this litigation, so it is overbroad and it is not reasonably calculated to lead to the discovery of admissible evidence. Defendants will not provide any information or produce any document relating to any drug other than Digitek® except where such information or document also reasonably relates to Digitek® or the manufacture of Digitek®. This Interrogatory is also vague and confusing as written, and is particularly vague with respect to the

undefined terms "alleged non-compliance" and "alleged non-compliance." Responding to an Interrogatory so overbroad in time and scope would be unduly burdensome for Defendants. Defendants also object to this Interrogatory to the extent it seeks information protected by the attorney-client privilege.

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way, and as such they join in the objections to this Interrogatory but not the substantive response.

Subject to the foregoing objections, Defendants respond as follows:

| FDA Document | Document Date | Alleged Non-Compliant Acts |
|---|---|---|
| FDA 483 | 2/8/2006 | Failure to report adverse drug experience reports relating to Digoxin. |
| FDA 483 | 8/10/2006 | The suitability of testing methods is not verified under actual conditions of use; deficiencies noted in cleaning validation studies. |
| Warning Letter | 8/15/2006 | Based on observations concluded in 2/2006, noted failure to comply with post-marketing ADE reporting requirements. |
| Warning Letter | 1/9/2007 | Based on FDA's observations concluded on 8/10/2006, WL stated cleaning validation studies are inadequate/ there is no assurance that equipment is adequately cleaned between the manufacture of different drug products. |
| Revised Warning Letter | 2/2/2007 | Revised 1/9/2007 letter removing certain references to other, non-Digoxin products and making no changes to observations relating to Digoxin. |
| FDA 483 | 5/20/2008 | Failure to reject product that fails to meet established specifications and quality control criteria. |
| FDA 483 | 5/21/2008 | Failure to timely submit 15-day reports to FDA. |

The above FDA documents and Actavis Totowa's responses to the same will be produced to Plaintiffs.

**INTERROGATORY NO. 9:**

Identify by Batch and/or Lot Number, all Digitek® that has been recalled, voluntary or otherwise, in the last five years. For each batch and/or lot identified, please state the date each

batch or lot was manufactured and describe in detail the reason for the recall including the facts relied upon by Defendants in each decision to institute a recall.

**ANSWER:**

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way, and as such they join in the objections to this Interrogatory but not the substantive response.

Subject to the foregoing objections, Actavis Totowa provides the following response: The only Digitek® recalled in the last five years were the following 171 batches of Digitek®, which were recalled on April 25, 2008.

| Packaged Batch # | Expiration Date | Manufacturing Date | Packaging Date |
|---|---|---|---|
| 60236A1 | Apr-08 | 4/20/2006 | 5/11/2006 |
| 60371A1 | Apr-08 | 4/21/2006 | 5/15/2006 |
| 60372A1 | Apr-08 | 4/22/2006 | 5/12/2006 |
| 60373A1 | Apr-08 | 4/24/2006 | 5/13/2006 |
| 60399A1 | May-08 | 5/4/2006 | 5/20/2006 |
| 60400A1 | May-08 | 5/4/2006 | 5/23/2006 |
| 60401A1 | May-08 | 5/5/2006 | 5/24/2006 |
| 60402A1 | May-08 | 5/6/2006 | 5/31/2006 |
| 60416A1 | May-08 | 5/16/2006 | 6/1/2006 |
| 60605A1 | Jun-08 | 6/28/2006 | 7/13/2006 |
| 60606A1 | Jun-08 | 6/29/2006 | 7/19/2006 |
| 60607A1 | Jun-08 | 6/29/2006 | 7/20/2006 |
| 60608A1 | Jul-08 | 7/12/2006 | 7/21/2006 |
| 60643A1 | Jul-08 | 7/12/2006 | 7/28/2006 |
| 60644A1 | Jul-08 | 7/13/2006 | 8/7/2006 |
| 60645A1 | Jul-08 | 7/14/2006 | 8/10/2006 |
| 60756A1 | Sep-08 | 9/1/2006 | 9/14/2006 |
| 60757A1 | Sep-08 | 9/5/2006 | 9/17/2006 |
| 60758A1 | Sep-08 | 9/6/2006 | 9/21/2006 |
| 60759A1 | Sep-08 | 9/7/2006 | 9/23/2006 |
| 60776A1 | Sep-08 | 9/12/2006 | 9/27/2006 |
| 60777A1 | Sep-08 | 9/12/2006 | 9/28/2006 |
| 60929A1 | Oct-08 | 10/26/2006 | 11/7/2006 |

| Packaged Batch # | Expiration Date | Manufacturing Date | Packaging Date |
|---|---|---|---|
| 60930A1 | Oct-08 | 10/27/2006 | 11/8/2006 |
| 60931A1 | Oct-08 | 10/28/2006 | 11/14/2006 |
| 60932A1 | Oct-08 | 10/30/2006 | 11/21/2006 |
| 60991A1 | Nov-08 | 11/10/2006 | 11/22/2006 |
| 60992A1 | Nov-08 | 11/11/2006 | 1/4/2007 |
| 60993A1 | Nov-08 | 11/13/2006 | 12/3/2006 |
| 60994A1 | Nov-08 | 11/14/2006 | 11/29/2006 |
| 61092A1 | Dec-08 | 12/8/2006 | 12/23/2006 |
| 70023A1 | Jan-08 | 1/8/2007 | 1/22/2007 |
| 70024A1 | Jan-08 | 1/9/2007 | 1/25/2007 |
| 70025A1 | Jan-08 | 1/10/2007 | 1/26/2007 |
| 70026A1 | Jan-08 | 1/19/2007 | 1/27/2007 |
| 70027A1 | Jan-08 | 1/22/2007 | 1/31/2007 |
| 70078A1 | Jan-08 | 1/23/2007 | 2/6/2007 |
| 70079A1 | Jan-08 | 1/29/2007 | 2/7/2007 |
| 70080A1 | Jan-08 | 1/30/2007 | 2/8/2007 |
| 70081A1 | Jan-08 | 1/31/2007 | 4/3/2007 |
| 70081A2 | Jan-08 | 1/31/2007 | 5/7/2007 |
| 70082A1 | Jan-08 | 2/1/2007 | 2/20/2007 |
| 70134A1 | Feb-08 | 2/9/2007 | 2/21/2007 |
| 70135A1 | Feb-08 | 2/10/2007 | 02/22/2007 |
| 70136A1 | Feb-08 | 2/11/2007 | 2/27/2007 |
| 70147A1 | Feb-08 | 2/18/2007 | 3/6/2007 |
| 70149A1 | Feb-08 | 2/20/2007 | 3/7/2007 |
| 70160A1 | Feb-08 | 2/21/2007 | 5/15/2007 |
| 70161A1 | Feb-08 | 2/22/2007 | 5/17/2007 |
| 70207A1 | Mar-08 | 3/12/2007 | 5/2/2007 |
| 70208A1 | Mar-08 | 3/13/2007 | 3/29/2007 |
| 70209A1 | Mar-08 | 3/14/2007 | 4/2/2007 |
| 70296A1 | Apr-08 | 4/3/2007 | 5/21/2007 |
| 70297A1 | Apr-08 | 4/4/2007 | 5/3/2007 |
| 70298A1 | Apr-08 | 4/12/2007 | 5/23/2007 |
| 70299A1 | Apr-08 | 4/13/2007 | 5/11/2007 |
| 70300A1 | Apr-08 | 4/14/2007 | 6/8/2007 |
| 70557A1 | Jul-08 | 7/6/2007 | 7/28/2007 |
| 70558A1 | Jul-08 | 7/7/2007 | 7/31/2007 |
| 70559A1 | Jul-08 | 7/9/2007 | 8/1/2007 |
| 70560A1 | Jul-08 | 7/10/2007 | 8/2/2007 |

| Packaged Batch # | Expiration Date | Manufacturing Date | Packaging Date |
|---|---|---|---|
| 70600A1 | Jul-08 | 7/19/2007 | 8/7/2007 |
| 70601A1 | Jul-08 | 7/25/2007 | 8/8/2007 |
| 70736A1 | Sep-08 | 9/9/2007 | 9/26/2007 |
| 70737A1 | Sep-08 | 9/10/2007 | 9/27/2007 |
| 70738A1 | Sep-08 | 9/11/2007 | 9/28/2007 |
| 70753A1 | Sep-08 | 9/16/2007 | 10/1/2007 |
| 70766A1 | Sep-08 | 9/18/2007 | 10/5/2007 |
| 70767A1 | Sep-08 | 9/19/2007 | 10/13/2007 |
| 70768A1 | Sep-08 | 9/25/2007 | 10/17/2007 |
| 70769A1 | Sep-08 | 9/26/2007 | 10/13/2007 |
| 70770A1 | Sep-08 | 9/27/2007 | 11/29/2007 |
| 70924A2 | Nov-08 | 11/14/2007 | 1/24/2008 |
| 70925A1 | Nov-08 | 11/15/2007 | 12/5/2007 |
| 70926A1 | Nov-08 | 11/19/2007 | 12/6/2007 |
| 70949A1 | Nov-08 | 11/19/2007 | 12/10/2007 |
| 70950A1 | Nov-08 | 11/20/2007 | 12/12/2007 |
| 70951A1 | Nov-08 | 11/21/2007 | 12/12/2007 |
| 70952A1 | Nov-08 | 11/24/2007 | 12/14/2007 |
| 70953A1 | Nov-08 | 11/25/2007 | 12/18/2007 |
| 71004A1 | Dec-08 | 12/10/2007 | 12/20/2007 |
| 71005A1 | Dec-08 | 12/10/2007 | 12/27/2007 |
| 80044A1 | Jan-08 | 1/16/2008 | 1/29/2008 |
| 80045A1 | Jan-08 | 1/17/2008 | 1/30/2008 |
| 80046A1 | Jan-08 | 1/18/2008 | 1/31/2008 |
| 80047A1 | Jan-08 | 1/19/2008 | 2/4/2008 |
| 80189A1 | Feb-08 | 2/29/2008 | 3/14/2008 |
| 80190A1 | Mar-08 | 3/1/2008 | 3/18/2008 |
| 80191A1 | Mar-08 | 3/3/2008 | 3/21/2008 |
| 80192A1 | Mar-08 | 3/4/2008 | 3/22/2008 |
| 80202A1 | Mar-08 | 3/6/2008 | 3/27/2008 |
| 80224A1 | Mar-08 | 3/14/2008 | 3/27/2008 |
| 80227A1 | Mar-08 | 3/17/2008 | 3/28/2008 |
| 60319A1 | Apr-08 | 4/8/2006 | 5/1/2006 |
| 60320A1 | Apr-08 | 4/10/2006 | 5/1/2006 |
| 60321A1 | Apr-08 | 4/11/2006 | 5/8/2006 |
| 60322A1 | Apr-08 | 4/11/2006 | 5/2/2006 |
| 60323A1 | May-08 | 5/30/2006 | 6/13/2006 |
| 60497A1 | May-08 | 5/30/2006 | 6/16/2006 |

| Packaged Batch # | Expiration Date | Manufacturing Date | Packaging Date |
|---|---|---|---|
| 60498A1 | May-08 | 5/31/2006 | 6/17/2006 |
| 60499A1 | Jun-08 | 6/1/2006 | 6/19/2006 |
| 60511A1 | Jun-08 | 6/5/2006 | 6/25/2006 |
| 60512A1 | Jun-08 | 6/5/2006 | 6/26/2006 |
| 60513A1 | Jun-08 | 6/6/2006 | 6/27/2007 |
| 60514A1 | Jun-08 | 6/9/2006 | 6/27/2006 |
| 60515A1 | Jun-08 | 6/10/2006 | 6/28/2006 |
| 60677A1 | Aug-08 | 8/1/2006 | 8/16/2006 |
| 60678A1 | Aug-08 | 8/2/2006 | 8/19/2006 |
| 60679A1 | Aug-08 | 8/2/2006 | 8/22/2006 |
| 60680A1 | Aug-08 | 8/3/2006 | 8/24/2006 |
| 60681A1 | Aug-08 | 8/4/2006 | 8/26/2006 |
| 60863A1 | Oct-08 | 10/4/2006 | 10/17/2006 |
| 60864A1 | Oct-08 | 10/4/2006 | 10/25/2006 |
| 60865A1 | Oct-08 | 10/5/2006 | 11 /1 /2006 |
| 61053A1 | Nov-08 | 11/30/2006 | 12/9/2006 |
| 61054A1 | Nov-08 | 12/1/2006 | 12/12/2006 |
| 61055A1 | Dec-08 | 12/3/2006 | 12/13/2006 |
| 61056A1 | Dec-08 | 12/10/2006 | 12/21/2006 |
| 61057A1 | Dec-08 | 12/11/2006 | 12/23/2006 |
| 61097A1 | Dec-08 | 12/12/2006 | 12/28/2006 |
| 61098A1 | Dec-08 | 12/14/2006 | 12/29/2006 |
| 61099A1 | Dec-08 | 12/20/2006 | 1/2/2007 |
| 61100A1 | Dec-08 | 12/21/2006 | 1/7/2007 |
| 61101A1 | Dec-08 | 12/22/2006 | 1/12/2007 |
| 61102A1 | Dec-08 | 12/27/2006 | 1/18/2007 |
| 61103A1 | Dec-08 | 12/28/2006 | 1/22/2007 |
| 61104A1 | Dec-08 | 12/29/2006 | 1/24/2007 |
| 70120A1 | Feb-08 | 2/5/2007 | 3/1/2007 |
| 70121A1 | Feb-08 | 2/6/2007 | 3/3/2007 |
| 70122A1 | Feb-08 | 2/7/2007 | 3/12/2007 |
| 70174A1 | Feb-08 | 2/26/2007 | 3/11/2007 |
| 70175A1 | Mar-08 | 3/2/2007 | 3/19/2007 |
| 70176A1 | Mar-08 | 3/3/2007 | 5/3/2007 |
| 70370A1 | May-08 | 5/1/2007 | 5/17/2007 |
| 70371A1 | May-08 | 5/2/2007 | 5/19/2007 |
| 70372A1 | May-08 | 5/3/2007 | 5/20/2007 |
| 70386A1 | May-08 | 5/4/2007 | 5/25/2007 |

| Packaged Batch # | Expiration Date | Manufacturing Date | Packaging Date |
|---|---|---|---|
| 70454A1 | Jun-08 | 6/1/2007 | 6/13/2007 |
| 70455A1 | Jun-08 | 6/2/2007 | 6/20/2007 |
| 70456A1 | Jun-08 | 6/4/2007 | 6/21/2007 |
| 70457A1 | Jun-08 | 6/10/2007 | 6/28/2007 |
| 70458A1 | Jun-08 | 6/11/2007 | 7/2/2007 |
| 70551A1 | Jul-08 | 7/5/2007 | 7/26/2007 |
| 70664A1 | Aug-08 | 8/7/2007 | 8/27/2007 |
| 70665A1 | Aug-08 | 8/8/2007 | 8/28/2007 |
| 70666A1 | Aug-08 | 8/9/2007 | 8/30/2007 |
| 70670A1 | Aug-08 | 8/10/2007 | 9/8/2007 |
| 70671A1 | Aug-08 | 8/16/2007 | 9/13/2007 |
| 70672A1 | Aug-08 | 8/20/2007 | 9/14/2007 |
| 70673A1 | Aug-08 | 8/21/2007 | 9/27/2007 |
| 70811A1 | Oct-08 | 10/5/2007 | 10/26/2007 |
| 70812A1 | Oct-08 | 10/6/2007 | 10/30/2007 |
| 70813A1 | Oct-08 | 10/15/2007 | 11/5/2007 |
| 70832A1 | Oct-08 | 10/16/2007 | 11/6/2007 |
| 70833A1 | Oct-08 | 10/17/2007 | 11/8/2007 |
| 70834A1 | Oct-08 | 10/18/2007 | 11/14/2007 |
| 70835A1 | Oct-08 | 10/20/2007 | 1/3/2008 |
| 70836A1 | Oct-08 | 10/22/2007 | 12/19/2007 |
| 71032A1 | Dec-08 | 12/16/2007 | 12/31/2007 |
| 71033A1 | Dec-08 | 12/19/2007 | 1/4/2008 |
| 71034A1 | Dec-08 | 12/20/2007 | 1/5/2008 |
| 71035A1 | Dec-08 | 12/29/2007 | 1/7/2008 |
| 71036A1 | Jan-08 | 1/2/2008 | 1/15/2008 |
| 71054A1 | Jan-08 | 1/9/2008 | 1/17/2008 |
| 80002A1 | Jan-08 | 1/10/2008 | 1/23/2008 |
| 80003A1 | Jan-08 | 1/11/2008 | 2/7/2008 |
| 80108A1 | Feb-08 | 2/4/2008 | 2/19/2008 |
| 80109A1 | Feb-08 | 2/5/2008 | 2/21/2008 |
| 80110A1 | Feb-08 | 2/6/2008 | 2/22/2008 |
| 80111A1 | Feb-08 | 2/8/2008 | 2/26/2008 |
| 80112A1 | Feb-08 | 2/9/2008 | 2/28/2008 |

The FDA was conducting a standard inspection of Actavis Totowa in 2008 regarding issues related validating transfer of manufacturing operations from the Little Falls facility to a

new facility. During that inspection, the FDA learned of circumstances involving Digitek® Batch 70924A that occurred in late 2007 and early 2008. During manufacturing, Batch 70924A was found to contain 20 tablets with approximately double the thickness of standard .125 mg tablet of Digitek® manufactured according to specification. Upon rigorous inspection, all such tablets were removed from Batch 70924 before final packaging and sale in 2008. Nevertheless, after discussions with the FDA in 2008 regarding Batch 70924A and the inspection thereof, in the context of the FDA's unrelated, ongoing inspection, Actavis Totowa decided to execute a Class I recall of all lots of Digitek® on the market within expiration. The recall of Digitek® was announced on April 25, 2008. To the best of Defendants' knowledge, none of the recalled Digitek® was defective. As expressed in the recall notice, the Digitek® recall was initiated in an abundance of caution by Actavis because of the possibility that tablets with approximately double the thickness may have been released into the market.

See documents related to Batch 70924, previously produced (ACTAV 000002112 - 000003336), as well as April 25, 2008 Digitek® recall notice available at [www.fda.gov/oc/po/firmrecalls/actavis04_08.html.

**INTERROGATORY NO. 10:**

Identify any governmental (including Congress) or regulatory investigation (including foreign investigations) into your activities relating to Digitek® manufacture or distribution, providing the following information:

a) The name of the entity which is or has conducted the investigation; and

b) The current status of the investigation.

**ANSWER:**

Defendants object to this Interrogatory because it is overbroad and it is not reasonably calculated to lead to the discovery of admissible evidence, in that it seeks information from other governmental agencies that do not follow applicable U.S. laws and regulations, and thus do not operate under the same standards as the FDA. This Interrogatory is also vague and confusing as written, and is particularly vague with respect to the undefined term "investigation…into your activities." This Interrogatory is also overbroad in that it is not limited to a relevant time frame. Defendants also object to the extent this Interrogatory seeks information protected by the attorney-client privilege.

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way, and as such they join in the objections to this Interrogatory but not the substantive response.

Subject to the foregoing objections, Defendants respond as follows: Defendants' response is limited to Digitek® manufactured and distributed in the United States as no Digitek® manufactured by Actavis Totowa was distributed outside of the United States. Defendants' Digitek® manufacturing activities have been examined in routine FDA regulatory inspections of Actavis Totowa's facilities, none of which were specifically aimed at Digitek®, but have not been the subject of any governmental or regulatory investigation.

**INTERROGATORY NO. 11:**

Identify all persons responsible for communicating with the FDA concerning Digitek® or any other drug manufactured at the Little Falls facility in the past five years and state their role within each of the respective Defendants' organization.

**ANSWER:**

Defendants object to this Interrogatory because it is it is not limited to Digitek®, the only product at issue in this litigation, so it is overbroad and it is not reasonably calculated to lead to the discovery of admissible evidence. Defendants will not provide any information or produce any document relating to any drug other than Digitek® except where such information or document also reasonably relates to Digitek® or the manufacture of Digitek®.

Subject to the foregoing objections, Defendants respond as follows:

Phyllis Lambridis, Vice President, US Quality & Compliance – Actavis, Inc.
Jasmine Shah, Vice President, Regulatory Affairs
Jacob Haroon, Senior Director, Regulatory Affairs

**INTERROGATORY NO. 12:**

Regarding the April, 2008 Class 1 nationwide recall of Digitek®, identify and describe in detail:

a) Each Defendant's involvement and/or role in the recall;

b) The person(s) within Defendants' organizations that were involved, directly or indirectly, in the decision to recall the Digitek®;

c) The person(s) responsible for making the final decision regarding the recall; and

d) Each fact relied upon by Defendants in the decision to recall Digitek®.

**ANSWER:**

a) Actavis Elizabeth LLC was not involved in the manufacture, testing, distribution, or the sale if Digitek® in any way. It had no involvement in the recall of Digitek®. Certain executive employees of Actavis Inc. were involved in discussions regarding the recall. Those persons obtained information from Actavis Totowa.

b) Phyllis Lambridis
Sigurdur Oli Olafsson
Robert Wessman
Divya Patel
John LaRocca

c) Phyllis Lambridis

d) Defendants object to this subpart because it is grossly overbroad. Subject to this objection, defendant Actavis Totowa responds as follows: See answer to Interrogatory No. 9.

**INTERROGATORY NO. 13:**

Identify each and every person who participated in any action taken by you to learn or investigate why the Recalled Digitek® was manufactured, produced, processed, compounded, formulated, labeled, and packaged with inconsistent amounts of the approved dose of the active ingredient.

**ANSWER:**

Defendants object to the extent this Interrogatory seeks information protected by the attorney-client privilege. Defendants also object to this Interrogatory because it assumes foundational facts that are not in evidence. This Interrogatory is also vague and confusing as written, and is particularly vague with respect to the undefined term "with inconsistent amounts of the approved dose of the active ingredient."

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way, and as such they join in the objections to this Interrogatory but not the substantive response.

Subject to the foregoing objections, Defendants respond as follows: To the best of Defendants' knowledge, there is currently no evidence that any of the Recalled Digitek® had inconsistent, out of specification amounts of approved the dose of the active pharmaceutical ingredient and Defendants are unaware of any Recalled Digitek® with any amount of active pharmaceutical ingredient that was outside of the specifications set forth in the ANDA for Digitek®.

**INTERROGATORY NO. 14:**

With regard to any testing of Digitek® conducted post recall, provide the following:

a) Identify pills tested by Lot/Batch number;

b) Results of testing for all pills tested to include date of testing; and,

c) Identify the labs utilized for testing.

**ANSWER:**

Defendants also object to this Interrogatory because it assumes foundational facts that are not in evidence.

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way, and as such they join in the objections to this Interrogatory but not the substantive response.

Subject to the foregoing objections, Defendants respond as follows:

a) None.

b) None.

c) None.

**INTERROGATORY NO. 15:**

With regard to non-conforming tablets observed in Lot 70924A, describe in detail how the pills were discovered.

**ANSWER:**

This Interrogatory is vague and confusing as written with respect to the undefined term "non-conforming tablets."

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way, and as such they join in the objections to this Interrogatory but not the substantive response.

Subject to the foregoing objections, Defendants respond as follows: During the packaging phase for Batch 70924A, employees observed several tablets on the channel counter that appeared to be larger than typical Digitek® manufactured to specifications. The packaging operation was stopped, and employees conducted a preliminary inspection of other buckets of compressed Digitek® that had not yet been packaged. Subsequently, quality assurance employees conducted two separate, rigorous inspections of the entire batch. Any Digitek® that had already been packaged was unpackaged to conduct these inspections. The details of this process are set forth in records related to Batch 70924, previously produced on April 2, 2009 (See ACTAV 000002112 - 000003336).

**INTERROGATORY NO. 16:**

With regard to non-conforming tablets observed in Lot 70924A, identify the person in the Quality Control Unit that was in charge of inspecting the entire Lot after discovery of non-conforming pills, and describe in detail how the inspection proceeded.

**ANSWER:**

This Interrogatory is vague and confusing as written with respect to the undefined term "non-conforming tablets."

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way, and as such they join in the objections to this Interrogatory but not the substantive response.

Subject to the foregoing objections, Defendants respond as follows: The person who was in charge of directing the inspection of the entire batch was Daniel Bitler. The initial part of the inspection consisted of spot checking various buckets of Digitek® that had not yet been packaged. Once several more out of specification tablets were found, the process was stopped and a formal inspection protocol was created. The entire batch was unpackaged and was subjected to a visual, tablet-by-tablet inspection by a team of employees. In total, 20 out of specification tablets were found.

The batch was then subjected to a "tightened AQL inspection." In this inspection the entire batch was subjected to a random test of 40 tablets from each of 33 full buckets, and 10 tablets from the partial 34th bucket. There were no additional out of specification tablets found during this inspection. The details concerning these inspections are set forth in the records relating to Batch 70924A, previously produced on April 2, 2009 (See (ACTAV 000002112 - 000003336).

**INTERROGATORY NO. 17:**

Identify any person, employee, manager, director or consultant that was "disciplined" for any reason, related to the manufacture, production, processing, compounding, testing, inspecting, labeling, packaging, marketing, advertising, distributing, selling, supplying and/or otherwise releasing Digitek® into the stream of commerce with more than the approved dose of the actual ingredient.

**ANSWER:**

Defendants object to this Interrogatory because it assumes foundational facts that are not in evidence. This Interrogatory is also vague and confusing as written with respect to the undefined term "more than the approved dose of the actual ingredient."

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way, and as such they join in the objections to this Interrogatory but not the substantive response.

Subject to the foregoing objections, Defendants respond as follows: prior to the recall and the commencement of this litigation Defendants concluded that no Digitek® with more than the approved dose of actual ingredient was placed into the stream of commerce. To the best of Defendants' knowledge, there is currently no evidence of such release.

**INTERROGATORY NO. 18:**

Identify all drugs or other products manufactured at the Little Falls facility in the last five years.

**ANSWER:**

Defendants object to this Interrogatory because it is it is not limited to Digitek®, the only product at issue in this litigation, so it is overbroad and it is not reasonably calculated to lead to the discovery of admissible evidence. Defendants will not provide any information or produce any document relating to any drug other than Digitek® except where such information or document also reasonably relates to Digitek® or the manufacture of Digitek®.

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way, and as such they join in the objections to this Interrogatory but not the substantive response.

Subject to the foregoing objections, Defendants respond as follows: Digitek® was manufactured at the Little Falls facility during the last five years. The identity of any other drug or product manufactured at the Little Falls facility during the last five years is beyond the scope of FRCP 26.

**INTERROGATORY NO. 19:**

Identify all drugs manufactured at the Little Falls facility that have had problems, irregularities or other issues concerning pill uniformity, pill strength or Good Manufacturing Practices of any kind in the past five years, including those mentioned in any FDA warning letters. For each drug identified, list and describe in detail any such problems or incidences.

**ANSWER:**

Defendants object to this Interrogatory because it is it is not limited to Digitek®, the only product at issue in this litigation, so it is overbroad and it is not reasonably calculated to lead to the discovery of admissible evidence. Defendants will not provide any information or produce any document relating to any drug other than Digitek® except where such information or document also reasonably relates to Digitek® or the manufacture of Digitek®. Defendants also object to the extent this Interrogatory seeks information protected by the attorney-client privilege.

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way, and as such they join in the objections to this Interrogatory but not the substantive response.

Subject to the foregoing objections, Defendants respond as follows: See Digitek® Annual Reports and Annual Product Reviews for 2003-2007, previously produced (ACTAV 000005279 - 000006268). See also, information on FDA 483 forms relating to Digitek® which will be produced.

**INTERROGATORY NO. 20:**

Identify all recalls instituted in the last five years that involve drugs manufactured at the Little Falls facility. For each recall, state the date and reason for the recall, listing separately each fact replied upon by Defendants in each decision to recall.

**ANSWER:**

Defendants object to this Interrogatory because it is it is not limited to Digitek®, the only product at issue in this litigation, so it is overbroad and it is not reasonably calculated to lead to the discovery of admissible evidence. Defendants will not provide any information or produce any document relating to any drug other than Digitek® except where such information or document also reasonably relates to Digitek® or the manufacture of Digitek®. Defendants also object to the extent this Interrogatory seeks information protected by the attorney-client privilege.

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way, and as such they join in the objections to this Interrogatory but not the substantive response.

Subject to the foregoing objections, Defendants respond as follows: Digitek® was recalled April 25, 2008. Any recall of any product other than Digitek® is beyond the scope of FRCP 26.

**INTERROGATORY NO. 21:**

With regard to the closure of the Little Falls facility, identify and describe all facts relied upon by Defendants in the decision to close the facility and describe in detail all activities that took place in the facility after it was closed.

**ANSWER:**

Defendants object to this Interrogatory because it is it is not limited to Digitek®, the only product at issue in this litigation, so it is overbroad and it is not reasonably calculated to lead to the discovery of admissible evidence. Defendants will not provide any information or produce any document relating to any drug other than Digitek® except where such information or document also reasonably relates to Digitek® or the manufacture of Digitek®. Defendants also object to the extent this Interrogatory seeks information protected by the attorney-client privilege.

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way, and as such they join in the objections to this Interrogatory but not the substantive response.

Subject to the foregoing objections, Defendants respond as follows: Actavis Totowa did not close the Little Falls facility. Actavis Totowa decided to temporarily suspend manufacturing operations at the Little Falls facility. The decision to suspend manufacturing operations was made after consultation with the FDA to allow the company to make modifications to the facility and to various aspects of the Company's manufacturing operations. Neither the decision to suspend manufacturing operations nor the modifications the Company made to the facility and to its manufacturing operations were related to Digitek®. Asking Defendants to "describe in detail all activities that took place in the facility after it closed" is grossly overbroad, has no relation to Digitek®, and seeks information that is beyond the scope of FRCP 26.

**INTERROGATORY NO. 22:**

Provide the name and address of any consultants you retained to advise on the closure of the Little Falls facility and describe the subject for which they were retained to consult.

**ANSWER:**

Defendants object to this Interrogatory because it is it is not limited to Digitek®, the only product at issue in this litigation, so it is overbroad and it is not reasonably calculated to lead to the discovery of admissible evidence. Defendants will not provide any information or produce any document relating to any drug other than Digitek® except where such information or document also reasonably relates to Digitek® or the manufacture of Digitek®. Defendants also object to the extent this Interrogatory seeks information protected by the attorney-client privilege.

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way, and as such they join in the objections to this Interrogatory but not the substantive response.

Subject to the foregoing objections, Defendants respond as follows: The decision to suspend manufacturing operations at the Little Falls facility was not related to Digitek® or the manufacture of Digitek® and, as a result, this Interrogatory seeks information that is beyond the scope of FRCP 26. Further answering, Defendants did not retain any consultants to "advise on the closure of the Little Falls facility."

**INTERROGATORY NO. 23:**

State whether you have ever prevented any Digitek® tablets from entering the market due to tablets not containing the correct dosage or correct amount of active ingredient. If the answer to this Interrogatory is yes, for time you prevented Digitek® tablets from entering the market, please list:

a) The date you prevented the Digitek® tablets from entering the market;

b) The reason you prevented the Digitek® tablets from entering the market;

c) Describe in detail how you determined that the Digitek® tablets were not suitable to be sold in the market.

**ANSWER:**

Defendants object to this Interrogatory because it is vague and confusing as written. Defendants also object to this Interrogatory because it is not limited to a relevant time frame, so it is overbroad and it is not reasonably calculated to lead to the discovery of admissible evidence.

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way, and as such they join in the objections to this Interrogatory but not the substantive response.

Subject to the foregoing objections, Defendants respond as follows: Yes. In the course of regular operations, certain batches were rejected for a variety of reasons. See responses to Interrogatories #15 and 16. See also Digitek® Annual Product Reviews for 2003-2007, previously produced (ACTAV 000005279 - 000006568). The Annual Product Review for 2008 will be produced.

**INTERROGATORY NO. 24:**

State whether you have ever prevented any drugs other than Digitek® that were manufactured at the Little Falls facility from entering the market due to the drugs not containing the correct dosage or correct amount of active ingredient. If the answer to this Interrogatory is yes, for time you prevented Digitek® tablets from entering the market, please list:

a) The name of the drug involved;

b) The date you prevented the drug from entering the market;

c) The reason you prevented the drug from entering the market;

d) Describe in detail how you determined that the drug was not suitable to be sold in the market.

**ANSWER:**

Defendants object to this Interrogatory because it is it is not limited to Digitek®, the only product at issue in this litigation, so it is overbroad and it is not reasonably calculated to lead to the discovery of admissible evidence. Defendants will not provide any information or produce any document relating to any drug other than Digitek® except where such information or document also reasonably relates to Digitek® or the manufacture of Digitek®. Defendants also object to the extent this Interrogatory seeks information protected by the attorney-client privilege.

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way.

**INTERROGATORY NO. 25:**

Give the names and addresses of all persons known to the party or counsel to be witnesses concerning the facts of the case and indicate whether or not written or recorded statements have been taken from the witnesses and indicate who has possession of any such statements.

**ANSWER:**

Defendants object to this Interrogatory to the extent it seeks information protected by the attorney-client privilege or the attorney work product doctrine. This Interrogatory is also vague and confusing with respect to the undefined term "facts of the case."

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way, and as such they join in the objections to this Interrogatory but not the substantive response.

Subject to the foregoing objections, Defendants respond as follows: Defendants have not yet selected the witnesses who will testify at the trial of this matter. Defendants will timely supplement this response prior to trial in compliance with the Court's pretrial orders.

**INTERROGATORY NO. 26:**

List the names, addresses and telephone numbers of any expert witnesses whom the party proposes to use as a witness at the trial of the case and for each, state in detail:

(a) his or her qualifications to testify;

(b) a detailed description of the subject matter on which each expert is expected to testify;

(c) a description of the facts on which each expert is expected to rely upon in testifying;

(d) set forth all opinions and conclusions to which each expert is expected to testify;

(e) set forth a summary of the grounds for each such opinion and conclusion;

(f) state whether any expert has conducted (or will conduct prior to trial) any investigation, inspection, examination and/or testing in connection with the issues involved in this suit and if so, the nature of such investigation, inspection, examination and/or testing, the results of same and the dates on which such work was performed;

(g) list the caption, jurisdiction and year of filing any suit in which said expert(s) has given court or deposition testimony in a case;

(h) provide a list of all documents that such expert has reviewed and all documents such expert intends to rely upon, testify to, reference or otherwise explain during the course of any testimony to be provided in this case; and

(i) provide the amounts of all sums paid by you to each expert for work on this case and an overall total paid to such expert or his company at anytime for work done on any case.

**ANSWER:**

Defendants object to this Interrogatory to the extent it seeks information protected by the attorney-client privilege or the attorney work product doctrine.

Subject to the foregoing objections, Defendants respond as follows: Defendants have not yet selected the witnesses who will testify at trial. Defendants will timely supplement this response prior to trial in compliance with the Court's pretrial orders.

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*Actavis Totowa LLC, Actavis Inc. and Actavis Elizabeth LLC*

# VERIFICATION

STATE OF New Jersey )
) ss:
COUNTY OF UNION )

Chris Young, being duly sworn, deposes and says:

I am the Managing Director of Operations of Actavis Totowa, LLC, a defendant in this action. The foregoing answers to Plaintiffs' First Set Interrogatories Directed to Defendants were prepared with the advice of counsel for Defendants, upon whose advice Defendants and I relied. Further, it was necessary to obtain information to prepare the responses from various sources, including Defendants' personnel and records. Subject to these qualifications, the foregoing responses are true and correct to the best of my knowledge, information and belief.

CHRIS YOUNG

Sworn to and subscribed before me this 22nd day of May, 2009

Kathleen F. Konops
Notary Public

KATHLEEN F. KONOPS
NOTARY PUBLIC OF NEW JERSEY
My Commission Expires 12/9/2010

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**
**CHARLESTON DIVISION**

**IN RE: DIGITEK®**

**PRODUCT LIABILITY LITIGATION**

**MDL NO. 1968**

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**THIS DOCUMENT RELATES TO ALL**

**CASES**

## CERTIFICATE OF SERVICE

I hereby certify that on May 22, 2009, I served "Answers of Defendants Actavis Inc., Actavis Totowa LLC and Actavis Elizabeth LLC to Plaintiffs' First Set of Interrogatories Directed to Defendants" via regular United States mail and electronic mail, upon Plaintiffs' Steering Committee, addressed as follows:

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: DIGITEK®

PRODUCT LIABILITY LITIGATION

MDL NO. 1968

THIS DOCUMENT RELATES TO ALL

CASES

## CERTIFICATE OF SERVICE

I hereby certify that on May 22, 2009, I served "Answers of Defendants Actavis Inc., Actavis Totowa LLC and Actavis Elizabeth LLC to Plaintiffs' First Set of Interrogatories Directed to Defendants" via regular United States mail and electronic mail, upon Plaintiffs' Steering Committee, addressed as follows:

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**IN THE UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**
**CHARLESTON DIVISION**

**IN RE: DIGITEK PRODUCT LIABILITY LITIGATION**

**MDL NO. 1968**

**THIS DOCUMENT RELATES TO ALL CASES**

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# DEFENDANTS ACTAVIS TOTOWA LLC, ACTAVIS INC., AND ACTAVIS ELIZABETH LLC'S RESPONSES TO PLAINTIFFS' SECOND SET OF INTERROGATORIES

Defendants Actavis Totowa LLC ("Actavis Totowa"), Actavis Inc. ("Actavis"), and Actavis Elizabeth LLC ("Actavis Elizabeth") ("Defendants") respond to Plaintiffs' Second Set of Interrogatories ("Interrogatories") as follows:

## RESERVATION OF RIGHTS

Defendants respond to Plaintiffs' Interrogatories to the best of their present knowledge, information, and belief. These responses are subject to additional or different information that discovery or further investigation may disclose. Defendants do not waive or intend to waive, by reason of their responses, their rights to: (1) revise, amend, or supplement these responses; (2) object on any ground to the use of documents produced for these responses for any purpose, in whole or in part, in this or any other proceeding, action, or matter; (3) object on any grounds, at any time, to other discovery procedures or requests relating to the subject matter of the Interrogatories; and (4) object on the grounds of admissibility to any documents produced in relation to the responses to these Interrogatories.

## GENERAL OBJECTIONS

Defendants make the following General Objections, which are in addition to, and incorporated within, each of the specific responses set forth below:

1. Defendants object to Plaintiffs' instructions and definitions to the extent they

attempt to enlarge the scope of permissible discovery under the Federal Rules of Civil Procedure, the Court's Pretrial Orders, and/or any other applicable rules.

2. Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way. As such, Defendants object to the Interrogatories, and the definitions and the instructions, to the extent they imply that Actavis Inc. and Actavis Elizabeth were involved with, or are primary custodians possessing any responsive documents relating to, the manufacture of Digitek®. Furthermore, Defendants assert that the responses set forth herein shall not be considered a waiver of any objection or an acknowledgement by Actavis Inc. and Actavis Elizabeth of involvement with, or possession of responsive documents relating to, the manufacture of Digitek®.

3. Defendants object to Plaintiffs' use of the term "Digitek" to the extent that it pertains to any product not manufactured, distributed, or marketed under the trade name Digitek®. Defendants further object to the extent that Plaintiffs' use of the term "Digitek" includes ingredients or products not manufactured, marketed, or distributed by a party to this lawsuit.

4. Defendants object to each Interrogatory to the extent it seeks any information or document relating to any drug other than Digitek®, the only product at issue in this litigation, which is not also reasonably related to the manufacture of Digitek® except to the extent disclosure of such information is required by the Court's Pre-trial Order #27 in this litigation ("PTO# 27").

5. Defendants object to each Interrogatory to the extent it seeks information or documents protected from disclosure or production by the attorney-client privilege, the attorney work-product doctrine, joint defense or common interest privilege, accountant-client privilege, or by any other privilege or doctrine available under federal or state law, whether statutory, regulatory, constitutional, or common law. Defendants further object to each Interrogatory to the

extent it seeks the disclosure of information or documents protected by statutes, regulations, common law, and the Federal Rules of Civil Procedure that are either absolutely protected from disclosure or production or which should be disclosed or produced only pursuant to an appropriate protective order. Inadvertent disclosure of any such information shall not constitute a waiver of any privilege or any other ground for objecting to discovery with respect to such information, nor shall inadvertent disclosure waive the right of Defendants to object to the use of any such information in any proceeding.

6. Defendants object to each Interrogatory to the extent it seeks discovery or production of confidential, trade secret, and/or proprietary information.

7. Defendants object to each Interrogatory to the extent it calls for the discovery of information already in Plaintiffs' possession, custody, or control, information that is publicly available, or information that is otherwise equally available to Plaintiffs, on grounds that such requests for information are unreasonably cumulative and duplicative, and that such information is obtainable from a source that is more convenient, less burdensome, and less expensive.

8. Defendants object to each Interrogatory to the extent it seeks documents or information relating to the manufacturing and production process of Digitek® batches other than the batches that were the subject of the 2008 Digitek® recall on the grounds that such Interrogatory is overly broad, unduly burdensome, seeks information that is not relevant to the subject matter of this action, and is not reasonably calculated to lead to the discovery of admissible evidence.

9. Defendants object to the extent any Interrogatory seeks information concerning a period of time prior or subsequent to the time period that any Plaintiff allegedly ingested Digitek® on the grounds that such Interrogatory is overly broad, unduly burdensome, and seeks information that is not relevant to the subject matter of this action and is not reasonably calculated to lead to the discovery of admissible evidence.

10. Defendants object to each Interrogatory to the extent it is directed to any entity other than Actavis Totowa LLC, Actavis Inc., and Actavis Elizabeth LLC.

11. Defendants object to each Interrogatory to the extent it is vague, ambiguous, confusing, argumentative, overly broad, oppressive, and/or requires an unduly burdensome and unnecessarily expensive search for, and disclosure of, documents that are neither relevant to the claim or defense of any party in this action nor reasonably calculated to lead to the discovery of admissible evidence.

12. Defendants object to each Interrogatory to the extent it is duplicative and cumulative.

13. Defendants object to each Interrogatory to the extent it calls for the disclosure of information or the production of documents not within Defendants' possession, custody, or control.

Defendants respond to these Interrogatories without waiving the foregoing objections (which shall be deemed to apply to each and every Interrogatory), or any other objections set forth herein.

**RESPONSES TO INTERROGATORIES**

**INTERROGATORY NO. 27:**

Please list the "In-house standards" and "USP standards" utilized for Digitek since 1999, the differences between the two standards and why one would be used over the other.

**RESPONSE TO INTERROGATORY NO. 27:**

Defendants object to this Interrogatory to the extent it is not limited to a relevant time frame, and is thus overbroad and is not reasonably calculated to lead to the discovery of admissible evidence. Responding to an interrogatory so overbroad in time and scope would be unduly burdensome for Defendants. This Interrogatory is also vague and confusing as written with respect to the undefined terms and phrases "In-house standards," "USP standards,"

"differences between the two standards," and "why one would be used over the other." This Interrogatory is also improper to the extent it seeks information about entities other than Defendants.

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way, and as such they join in the objections to this Interrogatory but not the substantive response.

Subject to the foregoing objections, Defendants respond as follows: Whether a USP Standard or an In-house Standard was used during testing of the recalled batches of Digitek® was within the discretion of Actavis. Typically, Actavis used an In-house Standard if a properly qualified In-house Standard was available and on hand when it was needed during the manufacturing process. See SOP DOI QC-046 "Reference Standard Program," previously produced (ACTAV 000064253 – ACTAV 000064289). The Standard used during the testing of each recalled batch of Digitek® is indicated in the records relating to the batch. The differences between the Standards used, if any, are reflected in records relating to production of the recalled batches. See previously produced records relating to Batch 70924 (ACTAV 000002112 – ACTAV 000003336), Batch 60236 (ACTAV 000003337 – ACTAV 000003991), Batch 60371 (ACTAV 000003992 – ACTAV 000004240), Batch 60372 (ACTAV 000004241 – ACTAV 000004969), Batch 60373 (ACTAV 000004970 – ACTAV 000005216), Batch 60319 (ACTAV 000006733 – ACTAV 000007669), Batch 60320 (ACTAV 000007670 – ACTAV 000007846), Batch 60321 (ACTAV 000007847 – ACTAV 000008141), Batch 60322 (ACTAV 000008142 – ACTAV 000008307), Batch 60323 (ACTAV 000008308 – ACTAV 000008581), Batch 60399 (ACTAV 000008582 – ACTAV 000008912), Batch 60400 (ACTAV 000008913 – ACTAV 000009153), Batch 60401 (ACTAV 000009154 – ACTAV 000009571), Batch 60402 (ACTAV 000009572 – ACTAV 000009834), Batch 60416 (ACTAV 000009835 – ACTAV 000010090), Batch 60497 (ACTAV 000010091 – ACTAV 000010249), Batch 60498 (ACTAV 000010250 –

ACTAV 000010480), Batch 60499 (ACTAV 000010481 – ACTAV 000010657), Batch 60511 (ACTAV 000010658 – ACTAV 000010863), Batch 60512 (ACTAV 000010864 – ACTAV 000011041), Batch 60513 (ACTAV 0000011042 – ACTAV 000011197), Batch 60514 (ACTAV 000011198 – ACTAV 000011422), Batch 60515 (ACTAV 000011423 – ACTAV 000011585), Batch 60605 (ACTAV 000011586 – ACTAV 000011939), Batch 60606 (ACTAV 000011940 – ACTAV 000012270), Batch 60607 (ACTAV 000012271 – ACTAV 000012658), Batch 60608 (ACTAV 0000012659 – ACTAV 000012920), Batch 60643 (ACTAV 000012921 – ACTAV 000013511), Batch 60644 (ACTAV 000013512 – ACTAV 000013856), Batch 60645 (ACTAV 000013857 – ACTAV 000014119), Batch 60677 (ACTAV 000014120 – ACTAV 000014304), Batch 60678 (ACTAV 000014305 – ACTAV 000014584), Batch 60679 (ACTAV 000014585 – ACTAV 000014833), Batch 60680 (ACTAV 000014834 – ACTAV 000015021), and Batch 60681 (ACTAV 000015022 – ACTAV 000015230), Batch 60756 (ACTAV 000018757 – ACTAV 000019129), Batch 60757 (ACTA000019130 – ACTAV 000019422), Batch 60758 (ACTA000019423 – ACTAV 000019684), Batch 60759 (ACTAV 000019685 – ACTAV 000020107), Batch 60776 (ACTAV 000020108 – ACTAV 000020405), Batch 60777 (ACTAV 000020406 – ACTAV 000020667), Batch 60863, ACTAV 000020668 – ACTAV 000020907), Batch 60864 (ACTAV 000020908 – ACTAV 000021106), Batch 60865 (ACTAV 000021107 – ACTAV 000021291), Batch 60929 (ACTAV 000021292 – ACTAV 000021623), Batch 60930 (ACTAV 000021624 – ACTAV 000021922), Batch 60931 (ACTAV 000021923 – ACTAV 000022282), Batch 60932 (ACTAV 000022283 – ACTAV 000022844), Batch 60991 (ACTAV 000022845 – ACTAV 000023116); (ACTAV 000024284 – ACTAV 000024285), Batch 60992 (ACTAV 000023117 – ACTAV 000023998), Batch 60993 (ACTAV 000023999 – ACTAV 000024352), Batch 60994 (ACTAV 000024353 – ACTAV 000024634), Batch 61053 (ACTAV 000024635 – ACTAV 000024796), Batch 61054 (ACTAV 000024797 – ACTAV 000025095), Batch 61055 (ACTAV 000025096 – ACTAV 000025328), Batch 61056 (ACTAV 000025329 –

ACTAV 000025494), Batch 61057 (ACTAV 000025495 – ACTAV 000025745), Batch 61092 (ACTAV 000025746 – ACTAV 000025985), Batch 61097 (ACTAV 000025986 – ACTAV 000026163), Batch 61098 (ACTAV 000026164 – ACTAV 000026402), Batch 61099 (ACTAV 000026403 – ACTAV 000026605), Batch 61100 (ACTAV 000026606 – ACTAV 000026993), Batch 61101 (ACTAV 000026994 – ACTAV 000027346), Batch 61102 (ACTAV 000027347 – ACTAV 000027639), Batch 61103 (ACTAV 000027640 – ACTAV 000027916), Batch 61104 (ACTAV 000027917 – ACTAV 000028089), Batch 70023 (ACTAV 000029372 – ACTAV 000030541), Batch 70024 (ACTAV 000030542 – ACTAV 000031026), Batch 70025 (ACTAV 000031027 – ACTAV 000031415), Batch 70026 (ACTAV 000031416 – ACTAV 000031779), Batch 70027 (ACTAV 000031780 – ACTAV 000032194), Batch 70078 (ACTAV 000032195 – ACTAV 000033348), Batch 70079 (ACTAV 000033349 – ACTAV 000033715), Batch 70080 (ACTAV 000033716 – ACTAV 000034116), Batch 70081 (ACTAV 000034117 – ACTAV 000034630), Batch 70082 (ACTAV 000034631 – ACTAV 000034995), Batch 70120 (ACTAV 000034996 – ACTAV 000035324), Batch 70121 (ACTAV 000035325 – ACTAV 000035608), Batch 70122 (ACTAV 000035609 – ACTAV 000035907), Batch 70134 (ACTAV 000035908 – ACTAV 000036297), Batch 70135 (ACTAV 000033298 – ACTAV 000036647), Batch 70136 (ACTAV 000033348 – ACTAV 000036996), Batch 70147 (ACTAV 000036997 – ACTAV 000037406), Batch 70149 (ACTAV 000037407 – ACTAV 000037696), Batch 70160 (ACTAV 000037697 – ACTAV 000038158), Batch 70161 (ACTAV 000038159 – ACTAV 000038643), Batch 70174 (ACTAV 000038644 – ACTAV 000038993), Batch 70175 (ACTAV 000038994 – ACTAV 000039349), Batch 70176 (ACTAV 000039350 – ACTAV 000039643), Batch 70207 (ACTAV 000039644 – ACTAV 000040211), Batch 70208 (ACTAV 000040212 – ACTAV 000040628), Batch 70209 (ACTAV 000040629 – ACTAV 000040982), Batch 70296 (ACTAV 000040983 – ACTAV 000041345), Batch 70297 (ACTAV 000041346 – ACTAV 000041651), Batch 70298 (ACTAV 000041652 – ACTAV 000042030), Batch 70299 (ACTAV 000042031 –

ACTAV 000042335), Batch 70300 (ACTAV 000042336 – ACTAV 000042632), Batch 70370 (ACTAV 000042633 – ACTAV 000043156), Batch 70371 (ACTAV 000043157 – ACTAV 000043403), Batch 70372 (ACTAV 000043404 – ACTAV 000043803), Batch 70386 (ACTAV 000043804 – ACTAV 000044081), Batch 70454 (ACTAV 000044082 – ACTAV 000044412), Batch 70455 (ACTAV 000044413 – ACTAV 000044678), Batch 70456 (ACTAV 000044679 – ACTAV 000045023), Batch 70457 (ACTAV 000045024 – ACTAV 000045302), Batch 70458 (ACTAV 000045303 – ACTAV 000045550), Batch 70551 (ACTAV 000045551 – ACTAV 000045939), Batch 70557 (ACTAV 000045940 – ACTAV 000046291), Batch 70558 (ACTAV 000046292 – ACTAV 000046601), Batch 70559 (ACTAV 000046602 – ACTAV 000046920), Batch 70560 (ACTAV 000046921 – ACTAV 000047255), Batch 70600 (ACTAV 000047256 – ACTAV 000047653), Batch 70601 (ACTAV 000047654 – ACTAV 000048017), Batch 70664 (ACTAV 000048018 – ACTAV 000048441), Batch 70665 (ACTAV 000048441 – ACTAV 000048820), Batch 70666 (ACTAV 000048821 – ACTAV 000049097), Batch 70670 (ACTAV 000049098 – ACTAV 000049553), Batch 70671 (ACTAV 000049554 – ACTAV 00004987), Batch 70672 (ACTAV 000049874 – ACTAV 000050183), Batch 70673 (ACTAV 000050184 – ACTAV 000050544), Batch 70736 (ACTAV 000050545 – ACTAV 000051062), Batch 70737 (ACTAV 000051063 – ACTAV 000051414), Batch 70738 (ACTAV 000051415 – ACTAV 000051754), Batch 70753 (ACTAV 000051755 – ACTAV 000052161), Batch 70766 (ACTAV 000052162 – ACTAV 000052611), Batch 70767 (ACTAV 000052611 – ACTAV 000053036), Batch 70768 (ACTAV 000053037 – ACTAV 000053547), Batch 70769 (ACTAV 000053548 – ACTAV 000053976), Batch 70770 (ACTAV 000053977 – ACTAV 000054490), Batch 70811 (ACTAV 000054491 – ACTAV 000054839), Batch 70812 (ACTAV 000054840 – ACTAV 000055172), Batch 70813 (ACTAV 000055173 – ACTAV 000055535), Batch 70832 (ACTAV 000055536 – ACTAV 000055793), Batch 70833 (ACTAV 000055794 – ACTAV 000056198), Batch 70834 (ACTAV 000056199 – ACTAV 000056489), Batch 70835 (ACTAV 000056490 –

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**INTERROGATORY NO. 28:**

Please list all of the raw ingredients and the manufacturer for each ingredient including active pharmaceutical ingredients and excipients used in the manufacture of Digitek for since 1999.

**RESPONSE TO INTERROGATORY NO. 28:**

Defendants object to this Interrogatory to the extent it is not limited to a relevant time frame, and is thus overbroad and is not reasonably calculated to lead to the discovery of admissible evidence. Responding to an interrogatory so overbroad in time and scope would be unduly burdensome for Defendants. This Interrogatory is also vague and confusing as written with respect to the undefined terms “raw ingredients” and “excipients.” This Interrogatory is also improper to the extent it seeks information about entities other than Defendants or seeks confidential, trade, secret, or proprietary information protected from disclosure under PTO #12.

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing,

distribution, or sale of Digitek® in any way, and as such they join in the objections to this Interrogatory but not the substantive response.

Subject to the foregoing objections, Defendants respond as follows: See the ANDA for Digitek®, previously produced to Plaintiffs and identified as ACTAV 000000095 – ACTAV 000002111.

**INTERROGATORY NO. 29:**

Was the chemical Pyridine used as a precursor or other substance in the purification, extraction, formulation, manufacture, and/or creation of the recalled chemical structural formulation known as Digitek®?

**RESPONSE TO INTERROGATORY NO. 29:**

Defendants object to this Interrogatory to the extent it is not limited to a relevant time frame, and is thus overbroad and is not reasonably calculated to lead to the discovery of admissible evidence. Responding to an interrogatory so overbroad in time and scope would be unduly burdensome for Defendants. This Interrogatory is also vague and confusing as written with respect to the undefined terms "precursor" and "recalled chemical structural formulation known as Digitek®." This Interrogatory is also improper to the extent it seeks information about entities other than Defendants or about the manufacturing or production activities of entities other than Defendants. Defendants object to this Interrogatory because it assumes foundational facts that are not in evidence. Defendants further object to this Interrogatory to the extent it seeks information that is not within Defendants' possession, custody, or control.

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way, and as such they join in the objections to this Interrogatory but not the substantive response.

Subject to the foregoing objections, Defendants respond as follows: Actavis Totowa does not use Pyridine in any aspect of the process of manufacturing Digitek®. To the extent Pyridine

was used by any supplier of any product to Actavis Totowa, it will be reflected in documents to be produced by Defendants on rolling basis, pursuant to PTO #16.

**INTERROGATORY NO. 30:**

Identify all elements, compounds, chemical substances (either organic or non-organic), synthesized compounds, metallic substances, nonmetallic substances, inert gases, and liquid gases which were used as a precursor or other substance in the purification, extraction, formulation, manufacture, and/or creation of the chemical structural formulation known as Digitek®.

**RESPONSE TO INTERROGATORY NO. 30:**

Defendants object to this Interrogatory to the extent it is not limited to a relevant time frame, and is thus overbroad and is not reasonably calculated to lead to the discovery of admissible evidence. Responding to an interrogatory so overbroad in time and scope would be unduly burdensome for Defendants. This Interrogatory is also vague and confusing as written with respect to the undefined terms "precursor" and "chemical structural formulation known as Digitek®." This Interrogatory is also improper to the extent it seeks information about entities other than Defendants or about the manufacturing or production activities of entities other than Defendants. Defendants further object to this Interrogatory because it assumes foundational facts that are not in evidence. Defendants further object to this Interrogatory to the extent it seeks information that is not within Defendants' possession, custody, or control.

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way, and as such they join in the objections to this Interrogatory but not the substantive response.

Subject to the foregoing objections, Defendants respond as follows: See the ANDA for Digitek®, previously produced to Plaintiffs and identified as ACTAV 000000095 – ACTAV 000002111. The elements, compounds, chemical substances (either organic or non-organic),

synthesized compounds, metallic substances, nonmetallic substances, inert gases, and liquid gases used by any supplier of any product to Actavis Totowa will be reflected in documents to be produced by Defendants on rolling basis, pursuant to PTO #16.

**INTERROGATORY NO. 31:**

What quality functions including anything related to quality control or quality assurance was conducted at the Riverview facility, including but not limited to all tests that are performed at this lab? If any, when did the move to Riverview take place?

**RESPONSE TO INTERROGATORY NO. 31:**

Defendants object to this Interrogatory to the extent it is not limited to information concerning Digitek®, the only product at issue in this litigation, and is not limited to a relevant time frame or relevant events, and is thus overbroad and is not reasonably calculated to lead to the discovery of admissible evidence. Responding to an interrogatory so overbroad in time and scope would be unduly burdensome for Defendants. Subject to the provisions of PTO #27, Defendants will not provide any information relating to any drug other than Digitek® except where such information or document also reasonably relates to Digitek® or the manufacture of Digitek®. The inclusion of the phrase "including but not limited to…" also makes this Interrogatory overbroad. This Interrogatory is also vague and confusing as written with respect to the undefined term "quality functions."

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way, and as such they join in the objections to this Interrogatory but not the substantive response.

Subject to the foregoing objections, Defendants respond as follows: Actavis Totowa began transferring overall quality control lab operations to the Riverview facility in August, 2007. Quality control testing of Digitek® at the Riverview facility, including testing of raw materials, blend samples, finished product, and stability testing, began in December, 2007. All

of Actavis Totowa's quality control lab functions now are conducted at Riverview. Quality assurance functions relating to certain validation batches of Digitek® that were manufactured as part of Actavis Totowa's efforts to transfer manufacturing operations to Riverview and have the FDA certify the Riverview facility were conducted beginning in December, 2007.

**INTERROGATORY NO. 32:**

What specific machines are used in the manufacture of Digitek® for since 1999, including manufacturer and internal Actavis machine number?

**RESPONSE TO INTERROGATORY NO. 32:**

Defendants object to this Interrogatory to the extent it is not limited to a relevant time frame, and is thus overbroad and is not reasonably calculated to lead to the discovery of admissible evidence. Responding to an interrogatory so overbroad in time and scope would be unduly burdensome for Defendants. This Interrogatory is also vague and confusing as written with respect to the undefined term "internal Actavis machine number." This Interrogatory is also improper to the extent it seeks information about entities other than Defendants.

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way, and as such they join in the objections to this Interrogatory but not the substantive response.

Subject to the foregoing objections, Defendants respond as follows: The equipment used to manufacture each batch of the recalled Digitek® is identified in the records relating to the manufacture and production of each batch. See previously produced records relating to Batch 70924 (ACTAV 000002112 – ACTAV 000003336), Batch 60236 (ACTAV 000003337 – ACTAV 000003991), Batch 60371 (ACTAV 000003992 – ACTAV 000004240), Batch 60372 (ACTAV 000004241 – ACTAV 000004969), Batch 60373 (ACTAV 000004970 – ACTAV 000005216), Batch 60319 (ACTAV 000006733 – ACTAV 000007669), Batch 60320 (ACTAV 000007670 – ACTAV 000007846), Batch 60321 (ACTAV 000007847 – ACTAV 000008141),

Batch 60322 (ACTAV 000008142 – ACTAV 000008307), Batch 60323 (ACTAV 000008308 – ACTAV 000008581), Batch 60399 (ACTAV 000008582 – ACTAV 000008912), Batch 60400 (ACTAV 000008913 – ACTAV 000009153), Batch 60401 (ACTAV 000009154 – ACTAV 000009571), Batch 60402 (ACTAV 000009572 – ACTAV 000009834), Batch 60416 (ACTAV 000009835 – ACTAV 000010090), Batch 60497 (ACTAV 000010091 – ACTAV 000010249), Batch 60498 (ACTAV 000010250 – ACTAV 000010480), Batch 60499 (ACTAV 000010481 – ACTAV 000010657), Batch 60511 (ACTAV 000010658 – ACTAV 000010863), Batch 60512 (ACTAV 000010864 – ACTAV 000011041), Batch 60513 (ACTAV 0000011042 – ACTAV 000011197), Batch 60514 (ACTAV 000011198 – ACTAV 000011422), Batch 60515 (ACTAV 000011423 – ACTAV 000011585), Batch 60605 (ACTAV 000011586 – ACTAV 000011939), Batch 60606 (ACTAV 000011940 – ACTAV 000012270), Batch 60607 (ACTAV 000012271 – ACTAV 000012658), Batch 60608 (ACTAV 0000012659 – ACTAV 000012920), Batch 60643 (ACTAV 000012921 – ACTAV 000013511), Batch 60644 (ACTAV 000013512 – ACTAV 000013856), Batch 60645 (ACTAV 000013857 – ACTAV 000014119), Batch 60677 (ACTAV 000014120 – ACTAV 000014304), Batch 60678 (ACTAV 000014305 – ACTAV 000014584), Batch 60679 (ACTAV 000014585 – ACTAV 000014833), Batch 60680 (ACTAV 000014834 – ACTAV 000015021), and Batch 60681 (ACTAV 000015022 – ACTAV 000015230), Batch 60756 (ACTAV 000018757 – ACTAV 000019129), Batch 60757 (ACTA000019130 – ACTAV 000019422), Batch 60758 (ACTA000019423 – ACTAV 000019684), Batch 60759 (ACTAV 000019685 – ACTAV 000020107), Batch 60776 (ACTAV 000020108 – ACTAV 000020405), Batch 60777 (ACTAV 000020406 – ACTAV 000020667), Batch 60863, ACTAV 000020668 – ACTAV 000020907), Batch 60864 (ACTAV 000020908 – ACTAV 000021106), Batch 60865 (ACTAV 000021107 – ACTAV 000021291), Batch 60929 (ACTAV 000021292 – ACTAV 000021623), Batch 60930 (ACTAV 000021624 – ACTAV 000021922), Batch 60931 (ACTAV 000021923 – ACTAV 000022282), Batch 60932 (ACTAV 000022283 – ACTAV 000022844),

Batch 60991 (ACTAV 000022845 – ACTAV 000023116); (ACTAV 000024284 – ACTAV 000024285), Batch 60992 (ACTAV 000023117 – ACTAV 000023998), Batch 60993 (ACTAV 000023999 – ACTAV 000024352), Batch 60994 (ACTAV 000024353 – ACTAV 000024634), Batch 61053 (ACTAV 000024635 – ACTAV 000024796), Batch 61054 (ACTAV 000024797 – ACTAV 000025095), Batch 61055 (ACTAV 000025096 – ACTAV 000025328), Batch 61056 (ACTAV 000025329 – ACTAV 000025494), Batch 61057 (ACTAV 000025495 – ACTAV 000025745), Batch 61092 (ACTAV 000025746 – ACTAV 000025985), Batch 61097 (ACTAV 000025986 – ACTAV 000026163), Batch 61098 (ACTAV 000026164 – ACTAV 000026402), Batch 61099 (ACTAV 000026403 – ACTAV 000026605), Batch 61100 (ACTAV 000026606 – ACTAV 000026993), Batch 61101 (ACTAV 000026994 – ACTAV 000027346), Batch 61102 (ACTAV 000027347 – ACTAV 000027639), Batch 61103 (ACTAV 000027640 – ACTAV 000027916), Batch 61104 (ACTAV 000027917 – ACTAV 000028089), Batch 70023 (ACTAV 000029372 – ACTAV 000030541), Batch 70024 (ACTAV 000030542 – ACTAV 000031026), Batch 70025 (ACTAV 000031027 – ACTAV 000031415), Batch 70026 (ACTAV 000031416 – ACTAV 000031779), Batch 70027 (ACTAV 000031780 – ACTAV 000032194), Batch 70078 (ACTAV 000032195 – ACTAV 000033348), Batch 70079 (ACTAV 000033349 – ACTAV 000033715), Batch 70080 (ACTAV 000033716 – ACTAV 000034116), Batch 70081 (ACTAV 000034117 – ACTAV 000034630), Batch 70082 (ACTAV 000034631 – ACTAV 000034995), Batch 70120 (ACTAV 000034996 – ACTAV 000035324), Batch 70121 (ACTAV 000035325 – ACTAV 000035608), Batch 70122 (ACTAV 000035609 – ACTAV 000035907), Batch 70134 (ACTAV 000035908 – ACTAV 000036297), Batch 70135 (ACTAV 000033298 – ACTAV 000036647), Batch 70136 (ACTAV 000033348 – ACTAV 000036996), Batch 70147 (ACTAV 000036997 – ACTAV 000037406), Batch 70149 (ACTAV 000037407 – ACTAV 000037696), Batch 70160 (ACTAV 000037697 – ACTAV 000038158), Batch 70161 (ACTAV 000038159 – ACTAV 000038643), Batch 70174 (ACTAV 000038644 – ACTAV 000038993), Batch 70175

(ACTAV 000038994 – ACTAV 000039349), Batch 70176 (ACTAV 000039350 – ACTAV 000039643), Batch 70207 (ACTAV 000039644 – ACTAV 000040211), Batch 70208 (ACTAV 000040212 – ACTAV 000040628), Batch 70209 (ACTAV 000040629 – ACTAV 000040982), Batch 70296 (ACTAV 000040983 – ACTAV 000041345), Batch 70297 (ACTAV 000041346 – ACTAV 000041651), Batch 70298 (ACTAV 000041652 – ACTAV 000042030), Batch 70299 (ACTAV 000042031 – ACTAV 000042335), Batch 70300 (ACTAV 000042336 – ACTAV 000042632), Batch 70370 (ACTAV 000042633 – ACTAV 000043156), Batch 70371 (ACTAV 000043157 – ACTAV 000043403), Batch 70372 (ACTAV 000043404 – ACTAV 000043803), Batch 70386 (ACTAV 000043804 – ACTAV 000044081), Batch 70454 (ACTAV 000044082 – ACTAV 000044412), Batch 70455 (ACTAV 000044413 – ACTAV 000044678), Batch 70456 (ACTAV 000044679 – ACTAV 000045023), Batch 70457 (ACTAV 000045024 – ACTAV 000045302), Batch 70458 (ACTAV 000045303 – ACTAV 000045550), Batch 70551 (ACTAV 000045551 – ACTAV 000045939), Batch 70557 (ACTAV 000045940 – ACTAV 000046291), Batch 70558 (ACTAV 000046292 – ACTAV 000046601), Batch 70559 (ACTAV 000046602 – ACTAV 000046920), Batch 70560 (ACTAV 000046921 – ACTAV 000047255), Batch 70600 (ACTAV 000047256 – ACTAV 000047653), Batch 70601 (ACTAV 000047654 – ACTAV 000048017), Batch 70664 (ACTAV 000048018 – ACTAV 000048441), Batch 70665 (ACTAV 000048441 – ACTAV 000048820), Batch 70666 (ACTAV 000048821 – ACTAV 000049097), Batch 70670 (ACTAV 000049098 – ACTAV 000049553), Batch 70671 (ACTAV 000049554 – ACTAV 00004987), Batch 70672 (ACTAV 000049874 – ACTAV 000050183), Batch 70673 (ACTAV 000050184 – ACTAV 000050544), Batch 70736 (ACTAV 000050545 – ACTAV 000051062), Batch 70737 (ACTAV 000051063 – ACTAV 000051414), Batch 70738 (ACTAV 000051415 – ACTAV 000051754), Batch 70753 (ACTAV 000051755 – ACTAV 000052161), Batch 70766 (ACTAV 000052162 – ACTAV 000052611), Batch 70767 (ACTAV 000052611 – ACTAV 000053036), Batch 70768 (ACTAV 000053037 – ACTAV 000053547), Batch 70769

(ACTAV 000053548 – ACTAV 000053976), Batch 70770 (ACTAV 000053977 – ACTAV 000054490), Batch 70811 (ACTAV 000054491 – ACTAV 000054839), Batch 70812 (ACTAV 000054840 – ACTAV 000055172), Batch 70813 (ACTAV 000055173 – ACTAV 000055535), Batch 70832 (ACTAV 000055536 – ACTAV 000055793), Batch 70833 (ACTAV 000055794 – ACTAV 000056198), Batch 70834 (ACTAV 000056199 – ACTAV 000056489), Batch 70835 (ACTAV 000056490 – ACTAV 000056780), Batch 70836 (ACTAV 000056781 – ACTAV 000057138), Batch 70925 (ACTAV 000057139 – ACTAV 000057468), Batch 70826 (ACTAV 000057469 – ACTAV 000057807), Batch 70949 (ACTAV 000057808 – ACTAV 000058172), Batch 70950 (ACTAV 000058173 – ACTAV 000058544), Batch 70951 (ACTAV 000058545 – ACTAV 000058899), Batch 70952 (ACTAV 000058900 - 000059181), Batch 70953 (ACTAV 000059182 – ACTAV 000059460), Batch 71004 (ACTAV 000059461 – ACTAV 000060005), Batch 71005 (ACTAV 000060006 – ACTAV 000060576), Batch 71032 (ACTAV 000060577 – ACTAV 000061024), Batch 71034 (ACTAV 000061025 – ACTAV 000061473), Batch 71035 (ACTAV 000061474 – ACTAV 000061945), Batch 80111 (ACTAV 000061946 – ACTAV 000062448), Batch 80191 (ACTAV 000062449 – ACTAV 000062685), Batch 80192 (ACTAV 000062686 – ACTAV 000062959). See also the ANDA for Digitek®, previously produced to Plaintiffs and identified as ACTAV 000000095 – ACTAV 000002111.

**INTERROGATORY NO. 33:**

What specific machines have been used in the testing of Digitek® for the past 5 years, including manufacturer, model number and internal Actavis machine number or equipment identification number, including but not limited to those machines used in raw material testing, in-process testing, finished product testing and stability testing?

**RESPONSE TO INTERROGATORY NO. 33:**

Defendants object to this Interrogatory to the extent it is not limited to a relevant time frame, and is thus overbroad and is not reasonably calculated to lead to the discovery of

admissible evidence. Responding to an interrogatory so overbroad in time and scope would be unduly burdensome for Defendants. The inclusion of the phrase "including but not limited to…" also makes this Interrogatory overbroad. This Interrogatory is also vague and confusing as written with respect to the undefined terms **"**internal Actavis machine number or equipment identification number." This Interrogatory is also improper to the extent it seeks information about entities other than Defendants.

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way, and as such they join in the objections to this Interrogatory but not the substantive response.

Subject to the foregoing objections, Defendants respond as follows: The following manufacturing testing equipment may have been used to test Digitek® at some point during the period of January 1, 2003 through the date of the recall of Digitek®, April 25, 2008. For the specific equipment used to test each specific batch of the recalled Digitek®, see the records relating to the production of the recalled batches, referenced in Defendants' response to Interrogatory No. 32.

**THICKNESS GAUGES**

**ACTIVE**

| System ID | Equipment Type | Manufacturer | Model |
|---|---|---|---|
| | | | |
| TG-0783 | Thickness Gauge | Mitutoyo | PK-0505 |
| TG-0784 | Thickness Gauge | Mitutoyo | PK-0505 |
| TG-0786 | Thickness Gauge | Mitutoyo | PK-0505 |
| TG-0967 | Thickness Gauge | Mitutoyo | PK-0505 (700-118) |
| TG-0973 | Thickness Gauge | Mitutoyo | PK-0505 |
| TG-0974 | Thickness Gauge | Mitutoyo | PK-0505 |
| TG-0975 | Thickness Gauge | Mitutoyo | PK-0505 |
| TG-0976 | Thickness Gauge | Mitutoyo | PK-0505 |
| TG-0977 | Thickness Gauge | Mitutoyo | PK-0505 (700-118) |
| TG-0978 | Thickness Gauge | Mitutoyo | PK-0505 |
| TG-0979 | Thickness Gauge | Mitutoyo | PK-0505 |
| TG-0980 | Thickness Gauge | Mitutoyo | PK-0505 (700-118) |
| TG-0981 | Thickness Gauge | Mitutoyo | 700-118 PK0505 |
| TG-0982 | Thickness Gauge | Mitutoyo | 700-118 PK0505 |

| | | | |
|---|---|---|---|
| TG-0983 | Thickness Gauge | Mitutoyo | 700-118 PK0505 |
| TG-0984 | Thickness Gauge | Mitutoyo | 700-118 PK0505 |
| TG-205920 | Thickness Gauge | Mitutoyo | PK0505 (700-118) |

**REMOVED FROM SERVICE**

| System ID | Equipment Type | Manufacturer | Model |
|---|---|---|---|
| | | | |
| TG-0785 | Thickness Gauge | Mitutoyo | PK-0505 |
| TG-0696 | Thickness Gauge | Mitutoyo | PK-0505 |
| TG-0968 | Thickness Gauge | Mitutoyo | PK-0505 |
| TG-0205299 | Thickness Gauge | Mitutoyo | PK-0505 |
| TG-0970 | Thickness Gauge | Mitutoyo | PK-0505 |
| TG-0971 | Thickness Gauge | Mitutoyo | PK-0505 |
| TG-0972 | Thickness Gauge | Mitutoyo | PK-0505 |

**HARDNESS TESTERS**

| System ID | Equipment Type | Manufacturer | Model |
|---|---|---|---|
| | | | |
| HD-251 | Hardness Tester | Vankel | VK-200 |
| HD-255 | Hardness Tester | Vankel | VK200 |
| HD-257 | Hardness Tester | Vankel | 40-2000 |
| HD-261 | Hardness Tester | Vankel | 40-2000 |
| HD-262 | Hardness Tester | Vankel | 40-2000 |
| HD-263 | Hardness Tester | Vankel | 40-2000 |
| HD-265 | Hardness Tester | Vankel | 40-2000 |
| HD-268 | Hardness Tester | Vankel | VK-200 |
| HD-3311 | Hardness Tester | Vankel | VK200 |
| HD-3312 | Hardness Tester | Vankel | VK200 |

**REMOVED FROM SERVICE**

| System ID | Equipment Type | Manufacturer | Model |
|---|---|---|---|
| | | | |
| HD-254 | Hardness Tester | Vankel | VK-200 |
| HD-258 | Hardness Tester | Vankel | VK-200 |
| HD-264 | Hardness Tester | Vankel | VK-200 |
| HD-253 | Hardness Tester | Vankel | VK-200 |

**SCALES**

**ACTIVE**

| System ID | Equipment Type | Manufacturer | Model |
|---|---|---|---|

| | | | |
|---|---|---|---|
| SC-0925 | Scale | Ohaus | AR1530 |
| SC-0930 | Scale | Ohaus | AR1530 |
| SC-0931 | Scale | Ohaus | AR1530 |
| SC-0939 | Scale | General | GE525 |
| SC-0940 | Scale | General | GE525 |
| SC-0982 | Scale | General | GE525 |
| SC-0985 | Scale | AND | GP60K |
| SC-0986 | Scale | AND | GF300G |
| SC-0987 | Scale | AND | GF300G |
| SC-0988 | Scale | AND | GF400G |
| SC-0990 | Scale | AND | GP60K |
| SC-0991 | Scale | AND | GP60K |
| SC-0992 | Scale | AND | GP12K |
| SC-0994 | Scale | General | GSE350 |
| SC-0995 | Scale | General | GSE350 |
| SC-0996 | Scale | General | GSE350 |
| SC-1153 | Scale | AND | GP60K |
| SC-1154 | Scale | AND | GP60K |
| SC-1156 | Scale | AND | GF300G |
| SC-1158 | Scale | AND | GP12K |
| SC-1159 | Scale | AND | GP12K |
| SC-1162 | Scale | AND | GSE355 |
| SC-1164 | Scale | Mettler Toledo | XS105DU |
| SC-3211 | Scale | AND | GP-12K |
| SC-3212 | Scale | AND | GP-12K |
| SC-3215 | Scale | GSE | 355 |
| SC-3216 | Scale | GSE | 355 |
| | | | |
| **FR-0269** | **Friabilator** | **Varian** | **P/N 45-2000** |

**REMOVED FROM SERVICE**

| System ID | Equipment Type | Manufacturer | Model |
|---|---|---|---|
| | | | |
| SC-238 | Scale | General | GE525 |
| SC-246 | Scale | General | GSE350 |
| SC-247 | Scale | General | GSE355 |
| SC-226 | Scale | Shimadzu | EB63SW |
| SC-235 | Scale | Shimadzu | EB63SW |
| SC-236 | Scale | General | GSE350 |
| SC-926 | Scale | Ohaus | AR1530 |
| SC-929 | Scale | Ohaus | AR1530 |
| SC-997 | Scale | GF | GF-200 |
| SC-998 | Scale | GF | GF-200 |
| SC-999 | Scale | General | GSE350 |
| SC-3214 | Scale | AND | GF-200 |

| | | | |
|---|---|---|---|
| SC-3218 | Scale | AND | GF-200 |
| SC-218 | Scale | Shimadzu | EB63SW |
| SC-239 | Scale | Shimadzu | EB63SW |
| SC-248 | Scale | Ohaus | TS-200 |
| SC-921 | Scale | General | GE510 |
| SC-932 | Scale | Setra | HP-60K |
| SC-934 | Scale | Setra | 12000C |
| SC-935 | Scale | General | GE525 |
| SC-936 | Scale | General | GE525 |
| SC-937 | Scale | General | GE525 |
| SC-938 | Scale | General | GE525 |
| SC-981 | Scale | General | GE525 |

Further answering, the following laboratory testing equipment is currently used by Actavis Totowa to test products and raw materials. Some or all of this equipment may have been used to test Digitek® or raw materials used to make Digitek® at some point during the period of January 1, 2003 through the date of the recall of Digitek®, April 25, 2008. For the specific equipment used to test each specific recalled batch of Digitek® or raw materials used to make the recalled batches of Digitek®, including equipment that is no longer being used for any purpose because it has been taken out of service, see the records relating to the production of the recalled batches, referenced in Defendants' response to Interrogatory No. 32, as well as Logs setting forth the use of such laboratory equipment, to be produced on a rolling basis pursuant to PTO #16.

**CURRENT LABORATORY TESTING EQUIPMENT**

| **Equipment Type** | **Instrument ID#** | **Model** | **Serial Number** | **Manufacturer** |
|---|---|---|---|---|
| Atomic Absorption | AA-01 | AAnalyst 100 | 040S1050103 | Perkin Elmer Corp. |
| Micron Air Jet Sieve | AJS-01 | Micron Sieves20 | 33303AJ028 | Hosokawa Micron |
| Micron Air Jet Sieve | AJS-02 | Micron Sieves35 | 08401AJ028 | Hosokawa Micron |
| Micron Air Jet Sieve | AJS-03 | Micron Sieves40 | 0203AJ366 | Hosokawa Micron |
| Micron Air Jet Sieve | AJS-04 | Micron Sieves50 | 03359246 | W.S. Tyler |
| | | | | |

| Equipment Type | Instrument ID# | Model | Serial Number | Manufacturer |
|---|---|---|---|---|
| Micron Air Jet Sieve | AJS-05 | Micron Sieves60 | 33303AJ616 | Hosokawa Micron |
| Micron Air Jet Sieve | AJS-06 | Micron Sieves100 | 33303AJ624 | Hosokawa Micron |
| Micron Air Jet Sieve | AJS-07 | Micron Sieves140 | 33303AJ219 | Hosokawa Micron |
| Micron Air Jet Sieve | AJS-08 | Micron Sieves200 | 33303AJ558 | Hosokawa Micron |
| Micron Air Jet Sieve | AJS-09 | Micron Sieves270 | 33303AJ452 | Hosokawa Micron |
| Micron Air Jet Sieve | AJS-10 | Micron Sieves325 | 33303AJ806 | Hosokawa Micron |
| Micron Air Jet Sieve | AJS-11 | Micron Sieves80 | 33303AJ644 | Hosokawa Micron |
| Micron Air Jet Sieve | AJS-12 | Micron Sieves200 | 33303AJ711 | Hosokawa Micron |
| Micron Air Jet Sieve | AJS-13 | Micron Sieves400 | 29702AJ226 | Hosokawa Micron |
| Micron Air Jet Sieve | AJS-14 | Micron Sieves200 | USSTD350711 | Newark Wire Cloth Co. |
| Micron Air Jet Sieve | AJS-15 | Micron Sieves325 | USSTD350741 | Newark Wire Cloth Co. |
| Micron Air Jet Sieve | AJS-16 | Micron Sieves100 | USSTD350714 | Newark Wire Cloth Co. |
| Bio-Dis Apparatus | BIODIS01 | Bio-Dis III<br><br>Heater/Circulator-VK750D | 18-1160-0307 | Varian Inc |
| Bio-Dis Apparatus | BIODIS02 | Bio-Dis III<br><br>Heater/Circulator-VK750D | 6-3801-0307 | Varian Inc |
| Balance | BL-01 | ME235S | 21505141 | Sartorius |
| Balance | BL-02 | ME235S | 21607316 | Sartorius |
| Balance | BL-03 | CP225D | 19504857 | Sartorius |
| Balance | BL-04 | CP225D | 21410219 | Sartorius |
| Balance | BL-05 | GF200 | 14675995 | AND |
| Balance | BL-06 | GF200 | 14675994 | AND |
| Balance | BL-07 | GF200 | 14671108 | AND |
| Balance | BL-08 | GF2000 | 14686019 | AND |
| Balance | BL-09 | ME-5 | 16202648 | Sartorius |
| Balance | BL-10 | CP225D | 16312859 | Sartorius |
| Balance | BL-11- | HR202i | 15200214 | AND |
| Balance | BL12 | HR202i | 15200395 | AND |
| Balance weight Kit | BLWKIT-01 | Class-1 | 70701 | Rice Lake |
| Balance weight Kit | BLWKIT-02 | Class-1 | 70702-70707 | Troemner |

| Equipment Type | Instrument ID# | Model | Serial Number | Manufacturer |
|---|---|---|---|---|
| Balance weight Kit | BLWKIT-03 | Class-1 | 41224 | Troemner |
| Balance weight Kit | BLWKIT-04 | Class-1 | 11441 to 11446 | Troemner |
| Balance weight Kit (Micro) | BLWKIT-05 | Class-0 | S654 | Troemner |
| Balance weight Kit (Micro) | WT2507 | Class-0 | S707 | Troemner |
| Digitrate Burette | Burette-01 | Jencons Digitrat 50mL | R9890 | Jencons |
| KFT/PAT Burette | Burette-02 | Brinkmann 806-10 Exchange Unit | 11240092 | Metrohm |
| KFT/PAT Burette | Burette-03 | Brinkmann 806-20 Exchange Unit | 10974899 | Metrohm |
| KFT/PAT Burette | Burette-04 | Brinkmann 506-20 Exchange Unit | 11141010 | Metrohm |
| KFT/PAT Burette | Burette-05 | Brinkmann 506-20 Exchange Unit | 11160580 | Metrohm |
| KFT/PAT Burette | Burette-06 | Brinkmann 506-50 Exchange Unit | 10540784 | Metrohm |
| KFT/PAT Burette | Burette-07 | Brinkmann 739-10 Exchange Unit | N/A | Metrohm |
| KFT/PAT Burette | Burette-08 | Brinkmann 739-20 Exchange Unit | N/A | Metrohm |
| KFT/PAT Burette | Burette-09 | Brinkmann 739-20 Exchange Unit | N/A | Metrohm |
| KFT/PAT Burette | Burette-10 | Brinkmann 739-20 Exchange Unit | N/A | Metrohm |
| NIST Traceable Resistors | CCKIT-01 | Conductivity Calibration Kit | 213 | Thermo Scientific |
| NIST Traceable Resistors | CCKIT-02 | Conductivity Calibration Kit | 268 | Thermo Scientific |
| Centrifuge | CF-01 | 5804 | 0012742 | Eppendrof |
| Conductivity Meter with Probe | CM-01 | 121400 with 013610MD and 013016MD | A04883 WITH G08/034 AND MS2/012 | Thermo Scientific |
| | | | | |

| Equipment Type | Instrument ID# | Model | Serial Number | Manufacturer |
|---|---|---|---|---|
| Digital Callipers | DC-01 | 3415CC | 80216263 | Control Company |
| Digital Callipers | DC-02 | 799A-12/300 | 08/110055-1 | Starrett |
| Digital Callipers | DC-03 | 799A-12/300 | 08/110053-1 | Starrett |
| Tap Density | DENT-01 | Tap Density | 5-2197-0307 | Varian Inc. |
| Tap Density | DENT-02 | 50-1000 | 5-1875-1002 | Varian Inc. |
| Digital Humidity/Temp. Meter | DHT-01 | 35519-045 | 72174616 | Control Company |
| Digital Humidity/Temp. Meter | DHT-02 | 35519-045 | 72174603 | Control Company |
| Digital Humidity/Temp. Meter | DHT-03 | 35519-045 | 72174602 | Control Company |
| Digital Humidity/Temp. Meter | DHT-04 | 35519-045 | 72174604 | Control Company |
| Digital Humidity/Temp. Meter | DHT-05 | 35519-045 | 72174859 | Control Company |
| Digital Humidity/Temp. Meter | DHT-06 | 35519-045 | 72224140 | Control Company |
| Digital Humidity/Temp. Meter | DHT-07 | 35519-045 | 72174608 | Control Company |
| Digital Humidity/Temp. Meter | DHT-08 | 35519-045 | 72174681 | Control Company |
| Digital Humidity/Temp. Meter | DHT-09 | 35519-045 | 72174606 | Control Company |
| Digital Humidity/Temp. Meter | DHT-10 | 35519-045 | 72174613 | Control Company |
| Digital Humidity/Temp. Meter | DHT-11 | 35519-045 | 72174588 | Control Company |
| Digital Humidity/Temp. Meter | DHT-12 | 35519-045 | 72224164 | Control Company |
| Dissolution Apparatus | DIS013 | VK 7000<br><br>Heater/circulator-VK750D | 1-7773-0307<br><br>6-3795-0307 | Varian Inc.<br>Varian Inc. |
| | | | | |

| Equipment Type | Instrument ID# | Model | Serial Number | Manufacturer |
|---|---|---|---|---|
| Dissolution Apparatus | DIS02 | 10-1200<br><br>Heater/circulator-VK750D | 1-4575-0498<br>6-3882-067 | Vankel Inc<br>Varian Inc |
| Dissolution Apparatus | DIS03 | Evolution 6300<br><br>TCS | 6301175<br><br>2133784 | Distek Inc<br><br>Distek Inc |
| Dissolution Apparatus | DIS04 | Evolution 6300<br><br>TCS | 6301193<br><br>2133905 | Distek Inc<br><br>Distek Inc |
| Dissolution Apparatus | DIS05 | Evolution 6300<br><br>TCS | 6301191<br><br>2133903 | Distek Inc<br><br>Distek Inc |
| Dissolution Apparatus | DIS06 | Evolution 6300<br><br>TCS | 6301192<br><br>2133904 | Distek Inc<br><br>Distek Inc |
| Dissolution Apparatus | DIS07 | 10-1600<br><br>Heater/circulator-VK750D | 1-5783-0401<br><br>6-3865-0507 | Vankel Inc<br><br>Varian Inc |
| Dissolution Apparatus | DIS08 | 10-1600<br><br>Heater/circulator-VK750D | 1-6145-0102<br><br>6-2710-0504 | Vankel Inc<br>Varian Inc |
| Dissolution Apparatus | DIS09 | 10-1920<br><br>65-3000 | 1-5784-0401<br><br>6-1975-0102 | Vankel Inc<br><br>Vankel Inc. |
| Dissolution Autosampler | DISAS-01 | Evolution 4300<br><br>Syringe Pump A/B | 4301439<br><br>SP01819/SP01820 | Distek Inc.<br><br>Distek Inc |
| Dissolution Autosampler | DISAS-02 | Evolution 4300<br><br>Syringe Pump A/B | 4301440<br><br>SP01821/SP01822 | Distek Inc.<br><br>Distek Inc |
| Dissolution Center gauge | DISCC-01 | 170 | 3117 | Distek Inc |
| Dissolution Height gauge | DISHC-01 | 180 | 11001 | Distek Inc |
| Dissolution Calibratin QAkit | DISQA-01 | QAII C | 24-0102-0707 | Varian Inc |
| Dry Keeper | DK-01 | None | 4578 | Scienceware |
| Dry Keeper | DK-02 | None | 4600 | Scienceware |
| Dry Keeper | DK-03 | None | 4584 | Scienceware |
| Dry Keeper | DK-04 | None | 4606 | Scienceware |
| Dry Keeper | DK-05 | None | 4577 | Scienceware |
| Dry Keeper | DK-06 | None | 4583 | Scienceware |

| Equipment Type | Instrument ID# | Model | Serial Number | Manufacturer |
|---|---|---|---|---|
| Dry Keeper | DK-07 | None | 4587 | Scienceware |
| Dry Keeper | DK-08 | None | 4580 | Scienceware |
| Digital Manometer | DM-001 | HHP242-015A | 0912000030 | Omega Engineering |
| Digital Manometer | DM-002 | HHP242-015A | 0912000031 | Omega Engineering |
| Digital Manometer | DM-003 | HHP242-015A | 0912000029 | Omega Engineering |
| Disintegration Apparatus | DT01 | VK 100 | 36-575-0307 | Varian Inc |
| Digital Thermometer w/Probe | DTH-003 | 1523/ 08500-96 | 9877117/T01 | Fluke/Cole Parmer |
| Digital Thermometer w/Probe | DTH-007 | TFX430/ TPX130 | 10408718/ 10401568 | EBRO |
| Digital Thermometer w/Probe | DTH-008 | TFX430/ TPX130 | 10408705/ 10401566 | EBRO |
| Digital Thermometer w/Probe | DTH-009 | TFX430/ TPX130 | 10408704/ 10401565 | EBRO |
| Digital Thermometer w/Probe | DTH-010 | TFX430/ TPX130 | 10408703/ 10401564 | EBRO |
| Digital Thermometer w/Probe | DTM-02 | 800024 | 060802157/ A02 | Sper Scientific |
| Digital Thermometer w/Probe | DTM-03 | OMEGA/ON-402-PP | 306985/ 08K27883 | Omega |
| Digital Thermometer w/Probe | DTM-04 | 1523-5627A | 9794037/ 821399 | Fluke |
| Digital Thermometer w/Probe | DTM-05 | 1523/5611T | 9762064/ A910507 | Fluke |
| Dissolution Vessel Washer | DW-01 | VIP400 | 4401052 | Distek Inc |
| Friabilator | FR01 | Friabilator | 4-2422-0107 | Varian Inc |
| Friabilator | FR-02 | 45-1000 | 4-2075-1002 | Vankel Inc |
| Freezer | FRZ-01 | MFP-2020 | WB70941341 -0707 | Lab Research Products |
| GC | GC-001 | 6890N COMBI PAL | CN10639012 127932 | Agilent |
| GC | GC-002 | 6890N COMBI PAL | CN10731008 128309 | LEAP Technology |

| Equipment Type | Instrument ID# | Model | Serial Number | Manufacturer |
|---|---|---|---|---|
| GC | GC-003 | 6890N<br><br>7683 B ALS<br><br>7683 ALS Tray<br><br>G1888 Headspace Sampler | CN10641031<br><br>CN63835694<br><br>CN63941255<br><br>IT00628001 | Agilent<br><br>Agilent<br><br>Agilent<br><br>Agilent |
| Interface Module (CG-Little Falls Facility) | GC17 | 900 | 8075252722 | PE Nelson |
| GC Clow Meter | GCFM-01 | ADM1000 | US07A31743 | Agilent/HP |
| Drying Oven | GDO-01 | FD53-UL | 07-19842 | Binder |
| Miele glassware Washer | GW-01 | G7883CD | 74324616 | Distek Inc |
| Height Gage | HG-01 | 3752 | 08137046 | Starrett |
| Hardness Tester | HG01 | VK-200 | 8-1868-0307 | Varian Inc |
| Hardness Tester | HG-02 | 40-2000 | 8-1002-0599 | Vankel Inc |
| Incufridge | ICF-01 | None | None | Revolutionary Science |
| Auto Titrator | KFT-01 | 795 | 1795001011190 | Brinkmann |
| Auto Titrator | KFT-02 | 702 SM | ON5-102 | Brinkmann |
| HPLC | LC001 | Alliance 2695 Seperation module<br><br>2487 UV-Vis Dual ** Absorbance Detector<br><br>Column Heater | CO7SM4618A<br><br>C07587805M<br><br>A07SMC471E | Waters Corp.<br><br>Waters Corp.<br><br>Waters Corp. |
| HPLC | LC002 | Alliance 2695 Seperation module<br><br>2487 UV-Vis Dual ** Absorbance Detector<br><br>Column Heater | C07SM4573A<br><br>C07487802M<br><br>A07SMC464E | Waters Corp.<br><br>Waters Corp.<br><br>Waters Corp. |
| | | | | |

| Equipment Type | Instrument ID# | Model | Serial Number | Manufacturer |
|---|---|---|---|---|
| HPLC | LC003 | Alliance 2695 Seperation module | C07SM4572A | Waters Corp. |
| | | 2487 UV-Vis Dual ** Absorbance Detector | C07487810M | Waters Corp. |
| | | Column Heater | A07SMC438 E | Waters Corp. |
| | | 2414 Refractive Index detector | B07214495M | Waters Corp. |
| HPLC | LC008 | Alliance 2695 Seperation module | F07SM4297A | Waters Corp. |
| | | 2487 UV-Vis Dual ** Absorbance Detector | G07487700M | Waters Corp. |
| | | Column Heater | E07SMC878E | Waters Corp. |
| HPLC | LC009 | Alliance 2695 Seperation module | F07SM4304A | Waters Corp. |
| | | 2487 UV-Vis Dual ** Absorbance Detector | G07487703M | Waters Corp. |
| | | Column Heater | E07SMC882E | Waters Corp. |
| HPLC | LC010 | LC-2010cHT | C2125420398 8LP | Shimadzu Corp. |
| HPLC | LC011 | LC-2010cHT | C2125440474 0 LP | Shimadzu Corp |
| HPLC | LC012 | LC-2010cHT | C2125440472 1LP | Shimadzu Corp |
| HPLC | LC013 | LC-2010cHT | C2125440472 3 LP | Shimadzu Corp |
| HPLC | LC014 | Alliance 2695 Seperation module | K07SM42141 A | Waters Corp. |
| | | 2489 UV-Vis | K0787E827M | Waters Corp. |

| Equipment Type | Instrument ID# | Model | Serial Number | Manufacturer |
|---|---|---|---|---|
| | | Detector | | |
| | | Column Heater | K07SMC572E | |
| | | 2414 Refractive Index detector | K07214041M | Waters Corp. |
| | | | | Waters Corp. |
| HPLC | LC015 | Alliance 2695 Seperation module | K07SM4251A | Waters Corp. |
| | | 2998 Photodiode Array Detector | L07998806N | Waters Corp. |
| | | Column Heater | K07SMC540E | Waters Corp. |
| HPLC | LC016 | Alliance 2695 Seperation module | K07SM4248A | Waters Corp. |
| | | 2489 UV-Vis Detector | K0787E812M | Waters Corp. |
| | | Column Heater | K07SMC538E | Waters Corp. |
| HPLC | LC017 | Alliance 2695 Seperation module | K07SM4245A | Waters Corp. |
| | | 2998 Photodiode Array Detector | K07998636N | Waters Corp. |
| | | Column Heater | K07SMC569E | Waters Corp. |
| HPLC | LC018 | Alliance 2695 Seperation module | K07SM4252A | Waters Corp. |
| | | 2489 UV-Vis Detector | K0787E878M | Waters Corp. |
| | | Column Heater | K07SMC553E | Waters Corp. |
| | | 2414 Refractive | K07214020M | Waters Corp. |

| Equipment Type | Instrument ID# | Model | Serial Number | Manufacturer |
|---|---|---|---|---|
| | | Index detector | | |
| HPLC | LC019 | Alliance 2695 Seperation module | K07SM4258 A | Waters Corp. |
| | | 2998 Photodiode Array Detector | L07998796N | Waters Corp. |
| | | Column Heater | K07SMC556 E | Waters Corp. |
| HPLC | LC020 | LC-2010cHT | C2125420398 1 LP | Shimadzu Corp. |
| HPLC | LC021 | LC-2010cHT | C2125420398 2 LP | Shimadzu Corp. |
| HPLC | LC022 | LC-2010cHT | C2125420398 4 LP | Shimadzu Corp. |
| HPLC | LC023 | LC-2010cHT | C2125440473 0 LP | Shimadzu Corp. |
| HPLC | LC024 | LC-2010cHT | C2125440472 7 LP | Shimadzu Corp. |
| HPLC | LC025 | LC-2010cHT | C2125440472 8 LP | Shimadzu Corp. |
| Micron Air Jet Sieve | MAJ-01 | N/A | 277097-71287 | Hosokawa Micron |
| Malvern Mastersizer | MAL-01 | MS-200 | MAL1009984 | Malvern Instruments Limited |
| | | Hydro S | MAL1010334 | Malvern Instruments Limited |
| | | Scirocco | MAL1010002 | Malvern Instruments Limited |
| Moisture Balance | MB-01 | MB45 | 1128023496 | Ohaus |
| Distek EZ Fill 4500 | MD-01 | ez Fill 4500 | 4501028 | Distek Inc |
| Distek EZ Fill 4500 | MD-02 | ez Fill 4500 | 4501029 | Distek Inc |
| Muffle Furnace | MF-01 | FB1415M | 12570702367 84 | Barnstead |
| Micrometer | MM-01 | C0030025 | N/A | Starrett |
| Melting Point Apparatus | MPA-01 | Optimelt | 78323 | Stanford Research System |
| | | | | |

| Equipment Type | Instrument ID# | Model | Serial Number | Manufacturer |
|---|---|---|---|---|
| Wrist Shaker | MS-01 | 75 | 183070763 | Burrell Scientific |
| Wrist Shaker | MS-02 | 75 | 183070925 | Burrell Scientific |
| Wrist Shaker | MS-03 | 75 | 183070916 | Burrell Scientific |
| Wrist Shaker | MS-04 | 75 | 183070859 | Burrell Scientific |
| Wrist Shaker | MS-05 | 75 | 183070855 | Burrell Scientific |
| Drying Oven | OV-01 | FD53-UL | 07-19841 | Binder |
| Drying Oven | OV -02 | FD53-UL | 07-19840 | Binder |
| Auto Titrator | PAT-01 | 798 MPT TITRINO | 1798001010264 | Brinkmann |
| Auto Titrator | PAT-02 | 716 DMS | 40104 | Brinkmann |
| Electronic Thermostat | PC-01 | PT31 | 25031109260808 | Rudolph Instruments |
| ELGA PureLab Ultra water System | PFW-01 | Uktra Analytic MK1 | UAB23584 | ELGA |
| pH Meter | pH-01 | SB70P | 005527 | VWR Symphony |
| pH Meter | pH-02 | SB70P | 005526 | VWR Symphony |
| pH Meter | pH-03 | SB70P | 005702 | VWR Symphony |
| pH Meter | pH-04 | SB70P | 005252 | VWR Symphony |
| Polarimeter | PM-01 | 341 | 8854 | Perkin Elmer Corp. |
| PhotoTachometer | PTC-01 | N/A | Q041969 | VWR |
| Pycnometer Thermometer | PTH-01 | N/A | 579467 | Kontes |
| Pycnometer Thermometer | PTH-03 | N/A | 579376 | Kontes |
| Digital Timer | QC-DT-01 | 5004CC | 80477275 | Control Company |
| Digital Timer | QC-DT-02 | 5004CC | 80477276 | Control Company |
| Digital Timer | QC-DT-03 | 5004CC | 80477277 | Control Company |
| Digital Timer | QC-DT-04 | 5004CC | 80477278 | Control Company |
| Digital Timer | QC-DT-05 | 5004CC | 80477279 | Control Company |
| Digital Timer | QC-DT-06 | 5004CC | 80477280 | Control Company |
| | | | | |

| Equipment Type | Instrument ID# | Model | Serial Number | Manufacturer |
|---|---|---|---|---|
| Digital Timer | QC-DT-07 | 5004CC | 80477281 | Control Company |
| Digital Timer | QC-DT-08 | 5004(( | 80477282 | Control Company |
| Digital Timer | QC-DT-09 | 5004CC | 80477283 | Control Company |
| Digital Timer | QC-DT-10 | 5004CC | 80477284 | Control Company |
| Digital Timer | QC-DT-11 | 5004CC | 80477285 | Control Company |
| Digital Timer | QC-DT-12 | 5004CC | 80477286 | Control Company |
| Digital Timer | QC-DT-13 | 5004CC | 80477287 | Control Company |
| Digital Timer | QC-DT-14 | 5004CC | 80477288 | Control Company |
| Digital Timer | QC-DT-15 | 5004CC | 80477289 | Control Company |
| Digital Timer | QC-DT-16 | 5004CC | 80477290 | Control Company |
| Digital Timer | QC-DT-17 | 5004CC | 80477291 | Control Company |
| Digital Timer | QC-DT-18 | 5004CC | 80477292 | Control Company |
| Digital Timer | QC-DT-19 | 5004CC | 80477293 | Control Company |
| Digital Timer | QC-DT-20 | 5004CC | 80477294 | Control Company |
| Digital Timer | QC-DT-21 | 5004CC | 80477295 | Control Company |
| Digital Timer | QC-DT-22 | 5004CC | 80477296 | Control Company |
| Digital Timer | QC-DT-23 | 5004CC | 80477297 | Control Company |
| Digital Timer | QC-DT-24 | 5004CC | 80477298 | Control Company |
| Digital Timer | QC-DT-25 | 5004CC | 80477299 | Control Company |
| Digital Timer | QC-DT-26 | 5004CC | 80477300 | Control Company |
| Digital Timer | QC-DT-27 | 5004CC | 80477301 | Control Company |
| Digital Timer | QC·DT·28 | 5004CC | 80477302 | Control Company |
| Digital Timer | QC-DT-29 | 5004CC | 80477303 | Control Company |
| | | | | |

| Equipment Type | Instrument ID# | Model | Serial Number | Manufacturer |
|---|---|---|---|---|
| Digital Timer | QC-DT-30 | 5004CC | 80477304 | Control Company |
| Digital Timer | QC-DT-31 | 5004CC | 80477305 | Control Company |
| Digital Timer | QC-DT-32 | 5004CC | 80477306 | Control Company |
| Digital Timer | QC-DT-33 | 5004CC | 80477307 | Control Company |
| Digital Timer | QC-DT-34 | 5004CC | 80477308 | Control Company |
| Digital Timer | QC-DT-35 | 5004CC | 80477309 | Control Company |
| Digital Timer | QC-DT-36 | 5004CC | 80477310 | Control Company |
| Digital Timer | QC-DT-37 | 5004CC | 80477311 | Control Company |
| Digital Timer | QC-DT-38 | 5004CC | 80477312 | Control Company |
| Digital Timer | QC-DT-39 | 5004CC | 80477313 | Control Company |
| Digital Timer | QC-DT-40 | 5004CC | 80477314 | Control Company |
| Digital Timer | QC-DT-41 | 5004CC | 80477315 | Control Company |
| Dlgital Timer | QC-DT-42 | 5004CC | 80477316 | Control Company |
| Digital Timer | QC-DT-43 | 5004CC | 80477317 | Control Company |
| Digital Timer | QC-DT-44 | 5004CC | 80477318 | Control Company |
| Digital Timer | QC-DT-45 | 5004CC | 80477319 | Control Company |
| Digital Timer | QC-DT-46 | 5004CC | 80477320 | Control Company |
| Digital Timer | QC-DT-47 | 5004CC | 80477321 | Control Company |
| Digital Timer | QC-DT-48 | 5004CC | 80477322 | Control Company |
| Digital Timer | QC-DT-49 | 5004CC | 80477323 | Control Company |
| Digital Timer | QC-DT-50 | 5004CC | 80477324 | Control Company |
| Ultrasonic (Sonicator) | QC-S1 | 8510R-DTH | RPC110735530F | Bransonic |
| Ultrasonic (Sonicator) | QC -S2 | 8510R-DTH | RPC050724117E | Bransonic |
| | | | | |

| Equipment Type | Instrument ID# | Model | Serial Number | Manufacturer |
|---|---|---|---|---|
| Ultrasonic (Sonicator) | QC-S3 | 8510R-DTH | RPC0207193 12E | Bransonic |
| Ultrasonic (Sonicator) | QC-S4 | 8510R-MT | RPA1005958 08E | Bransonic |
| Ultrasonic (Sonicator) | QC-S5 | 8510R-MT | RP Ai 00154883 E | Bransonic |
| 262-0066"1 150MM Rule | RC-01 | None | 500410524 | Engineering |
| Conductivity/Resistivity Meter | RES02 | 200CR | 607070017 | Mettler Toledo Thornton |
| Refractometer | RF-01 | 334610 | 345K018001 | Thermo Electron Corporation |
| Refrigerator | RFG-01 | LRP - 26 | 1-4844204-0707 | Lab Research Products |
| Radio/ Photo Meter | RPM-01 | IL1400A<br><br>UV/VIS Detector – SEL033 | 6588<br><br>7265/7255 | International Light<br><br>International Light |
| Photochemical Reactor | RPR-01 | None | None | N/A |
| Ro-Tap | RTSS-01 | E | 16040 | W.S. Tyler |
| Sonic Sifter | SS-01 | L3P | 6117 | Advantech Mfg. |
| Sonic Sifter Sieve | SSS-Oi | Sonic Sifter Sieve20 | 20C7 | AdvanTech |
| Sonic Sifter Sieve | 555-02 | Sonic Sifter Sieve40 | 40D7 | AdvanTech |
| Sonic Sifter Sieve | 555-03 | Sonic Sifter Sieve60 | 60F7 | AdvanTech |
| Sonic Sifter Sieve | 555-04 | Sonic Sifter Sieve80 | BOF7 | AdvanTech |
| Sonic Sifter Sieve | 555-05 | Sonic Sifter Sieve100 | 100F7 | AdvanTech |
| Sonic Sifter Sieve | 555-06 | Sonic Sifter Sieve120 | 120F7 | AdvanTech |
| 50nic Sifter Sieve | 555-07 | Sonic Sifter Sieve140 | 140B7 | AdvanTech |
| Sonic Sifter Sieve | 555-08 | Sonic Sifter Sieve170 | 170G7 | AdvanTech |
| Sonic Sifter Sieve | SSS-09 | Sonic Sifter Sieve200 | 200F7 | AdvanTech |
| Sonic Sifter Sieve | 555-10 | Sonic Sifter Sieve230 | 230£7 | AdvanTech |
| | | | | |

| Equipment Type | Instrument ID# | Model | Serial Number | Manufacturer |
|---|---|---|---|---|
| Sonic Sifter Sieve | S5S-11 | Sonic Sifter Sieve270 | 270F7 | AdvanTech |
| Sonic Sifter Sieve | 555-12 | Sonic Sifter Sieve325 | 325£7 | AdvanTech |
| Scott Volumeter | SV -01 | None | N/A | N/A |
| Scott Volumeter | SV-02 | None | N/A | NJA |
| Steam Water bath | SWB-01 | None | 603081453 | Precision |
| Tachometer | TC-01 | 4262 | 61700941 | Control Company |
| Long Stem Thermometer | QC-TH-01 | 4352CC | 72515219 | Control Company |
| Long Stem Thermometer | QC-TH-02 | 4352CC | 72515246 | Control Company |
| Long Stem Thermometer | QC-TH-04 | 4352CC | 72515252 | Control Company |
| Long Stem Thermometer | QC- TH-05 | 4352CC | 72515259 | Control Company |
| Long Stem Thermometer | QC- TH-06 | 4352CC | 72515262 | Control Company |
| Long Stem Thermometer | QC- TH-07 | 4352CC | 72515264 | Control Company |
| Long Stem Thermometer | QC- TH-08 | 4352CC | 72515266 | Control Company |
| Long Stem Thermometer | QC- TH-09 | 4352CC | 72515277 | Control Company |
| Long Stem Thermometer | QC-TH-10 | 4352CC | 72515282 | Control Company |
| Long Stem Thermometer | QC-TH-11 | 4352CC | 72515288 | Control Company |
| Long Stem Thermometer | QC-TH-12 | 4352CC | 72523291 | Control Company |
| Long Stem Thermometer | TH·13 | 4352CC | 80285745 | Control Company |
| Long Stem Thermometer | TH ·14 | 4352CC | 80285748 | Control Company |
| Long Stem Thermometer | TH-15 | 4352CC | 80285749 | Control Company |
| Long Stem Thermometer | TH·16 | 4352CC | 80285751 | Control Company |
| Long Stem Thermometer | TH-17 | 4352CC | 80285753 | Control Company |
| Long Stem Thermometer | TH·19 | 4352CC | 80285756 | Control Company |
| Long Stem Thermometer | TH-20 | 4352CC | 80285757 | Control Company |
| Long Stem Thermometer | TH-21 | 4352CC | 80285760 | Control Company |

| Equipment Type | Instrument ID# | Model | Serial Number | Manufacturer |
|---|---|---|---|---|
| Long Stem Thermometer | TH - 22 | 4352CC | 80285770 | Control Company |
| Long Stem Thermometer | TH-23 | 4352CC | 80285773 | Control Company |
| Long Stem Thermometer | TH-24 | 4352CC | 72335582 | Control Company |
| Tyler Sieve | TS-02 | Tyler Sieve20 | 07296708 | W.S.Tyler |
| Tyler Sieve | TS-03 | Tyler Sieve40 | 07296709 | W.S.Tyler |
| Tyler Sieve | TS-04 | Tyler Sieve60 | 07296710 | W.S.Tyler |
| Tyler Sieve | TS-05 | Tyler Sieve80 | 07296711 | W.S.Tyler |
| Tyler Sieve | TS-07 | Tyler Sieve140 | 07296713 | W.S.Tyler |
| Tyler Sieve | TS-08 | Tyler Sieve200 | 07296714 | W.S.Tyler |
| Tyler Sieve | TS-10 | Tyler Sieve400 | 07296716 | W.S.Tyler |
| Tyler Sieve | TS-11 | Tyler Sieve25 | 03012208 | Retsch |
| Tyler Sieve | TS-12 | Tyler Sieve30 | 08129238 | W.S.Tyler |
| Tyler Sieve | TS-13 | Tyler Sieve35 | 04021202 | Retsch |
| Tyler Sieve | TS-14 | Tyler SieveSO | 04026783 | Retsch |
| Tyler Sieve | TS-15 | Tyler Sieve325 | 06419162 | W.S.Tyler |
| Tyler Sieve | TS-16 | Tyler Sieve325 | USSTD70301 | Newark Wire Cloth Company |
| Tyler Sieve | TS-17 | Tyler Sieve100 | USSTD71100 | Newark Wire |
| Tyler Sieve | TS-18 | Tyler Sieve60 | USSTD70501 | Newark Wire |
| Tyler Sieve | TS-19 | Tyler Sieve200 | USSTD71200 | Newark Wire |
| Tyler Sieve | TS- 20 | Tyler Sieve18 | USSTD70018 | Newark Wire |
| Tyler Sieve | TS-21 | Tyler Sieve40 | USSTD70203 | Newark Wire |
| Tyler Sieve Shaker | TSS·01 | RX-86 | 573 | W.S.Tyler |
| UV-Vis Spectophotometer | UV01 | UV-1700 | A1102443680 0CS | Shimadzu Corp. |
| Syringe Sipper | UVS01 | Syringe Sipper N | A1101440029 5 | Shimadzu Corp. |
| UV-Vis Spectophotometer | UV02 | UV-1601 | A1 07540021 98 LP | Shimadzu Corp. |
| Syringe Sipper | UVS02 | Syringe Sipper N | A1101440026 6 TK | Shimadzu Corp. |
| UV-Vis Spectophotometer | UV-03 | UV-1601 | Ai 07540851 09 SM | Shimadzu Corp. |
| Syringe Sipper | UVS03 | Syringe Sipper N | A1101440033 7 TK | Shimadzu Corp. |
| UV Light Chamber | UVL -01 | None | 1405 | Camag |
| Density Cup | VDC-01 | 20-0009 | 06-1 84 | Steiner enterprises Inc |
| Density Cup | VDC -02 | 20-0009 | 07-056 | Steiner enterprises Inc |
| Vacuum/Pressur Gauge | VG-01 | 3166 | 61844164 | Control Company |

| Equipment Type | Instrument ID# | Model | Serial Number | Manufacturer |
|---|---|---|---|---|
| Vaccum Oven | VO-01 | ADP21 | ADP200B7400013 | Yamato |
| Vaccum Oven | VO-OZ | ADPZ1 | ADP200B7XOO186 | Yamato |
| Vaccum Oven | VO-03 | ADP21 | ADP200B7XOO188 | Yamato |
| Water bath | WB-01 | 18012 | 1475070706676 | Barnstead international |
| Water bath | WB-03 | 205 | 1600080453541 | Fisher Scientific lnc |

**INTERROGATORY NO. 34:**

For each machine, listed in your answers to the above interrogatories, please list what other products each machine is used to manufacture and/or test.

**RESPONSE TO INTERROGATORY NO. 34:**

Defendants object to this Interrogatory to the extent it is not limited to information concerning Digitek®, the only product at issue in this litigation, and is not limited to a relevant time frame or relevant events, and is thus overbroad and is not reasonably calculated to lead to the discovery of admissible evidence. Responding to an interrogatory so overbroad in time and scope would be unduly burdensome for Defendants. Subject to the provisions of PTO #27, Defendants will not provide any information relating to any drug other than Digitek® except where such information or document also reasonably relates to Digitek® or the manufacture of Digitek®. This Interrogatory is also vague and confusing as written with respect to the undefined phrase "used to manufacture and/or test." This Interrogatory is also improper to the extent it seeks information about entities other than Defendants.

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way, and as such they join in the objections to this Interrogatory but not the substantive response.

Subject to the foregoing objections, Defendants respond as follows: See Equipment

Usage and Cleaning Logs, previously produced (ACTAV 000015231 – ACTAV 000018681; ACTAV – 0028090 – ACTAV 000028177; ACTAV 000062903 – ACTAV 000062943). Additional documents containing information that is responsive to this Interrogatory, if any, will be produced on a rolling basis pursuant to PTO #16.

**INTERROGATORY NO. 35:**

Please list all analysts that performed any testing since 1999 on Digitek® or the component parts or raw materials used in the manufacturing of Digitek®. For each analyst named, please state whether they are currently employed and the bates numbers for that person's corresponding lab notebook.

**RESPONSE TO INTERROGATORY NO. 35:**

Defendants object to this Interrogatory to the extent it is not limited to a relevant time frame, and is thus overbroad and is not reasonably calculated to lead to the discovery of admissible evidence. Responding to an interrogatory so overbroad in time and scope would be unduly burdensome for Defendants. This Interrogatory is also vague and confusing as written with respect to the undefined term "analyst." This Interrogatory is also improper to the extent it seeks information about entities other than Defendants and information that is beyond the possession, custody, and control of Defendants.

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way, and as such they join in the objections to this Interrogatory but not the substantive response.

Subject to the foregoing objections, Defendants respond as follows: To the best of Defendants' knowledge, the following individuals have been involved with testing of products or raw materials for Actavis Totowa at some point during the period of January 1, 2003 through the date of the recall of Digitek®, April 25, 2008, and may have been involved in testing Digitek® or the raw materials used to make Digitek®. The identity of some former employees of Amide

(predecessor to Actavis Totowa) who performed testing of products or raw materials and who may have performed testing of Digitek® or the raw materials used to make Digitek® is not known to and is not readily accessible to Defendants. If Defendants learn of additional responsive information, Defendants will timely supplement this response.

Current Employees

1. Jigneshkumar C. Soni
2. Dilipkumar R Patel
3. Jitendra D Patel
4. Manish I Patel
5. Bakul J Shah
6. Kalpesh H Shah
7. Jyotiben P Panchal
8. Harshika K Patel
9. Majlinda L Xhelo
10. Pranathi Neelam
11. Kwame Adjei
12. Anilkumar Patel
13. Dinesh R Patel
14. Maheshbhai S Patel
15. Nimeshkumar N Patel
16. Ritaben R Patel
17. Kazi M Rahman
18. Girishchandra B Upadhyay
19. Daniel J Burns
20. Kishor N Lad

21. Harshad A Patel
22. Hemlataben Patel
23. Ketankumar A Patel
24. Narendrakumar J Patel
25. Paresh M Patel
26. Sanjay N Patel
27. Jigneshkumar I Desai
28. Pratik P Kalaria
29. Devang B Patel
30. Pratik S Patel
31. Sunilkumar S Patel
32. Kaushik R Soni
33. Hemang P Kapadia
34. Gaurang L Pandya
35. Tarak M Shah
36. Chintan M Joshi
37. Tushar R Malkan
38. Justine V Parmar
39. Chiragbhai S Patel
40. Hiteshkumar N Patel
41. Jitenbhai R Patel
42. Mahendrakumar B Patel
43. Nimishkumar C Patel
44. Madhulika Joshi
45. Haresh G Patel

46. Sonal M Patel

47. Umang B Pandya

48. Inaben M Patel

49. Nikunjkumar J Patel

50. Rajendrakumar P Patel

51. Saurabhkumar J Patel

52. Shitalbahen H Patel

53. Emiliya I Antonova

54. Chetan J Rana

55. Kinjal M Maniar

56. Hardik V Parikh

57. Chirag V Patel

58. Dilipkumar C Patel

59. Girish T Rana

60. Hemantkumar P Rao

61. Shilpa D Patel

62. Nikhil B Patel

63. Riteshkumar S Patel

Former Employees

64. Nileshkumar C Patel

65. Bharat G Rana

66. Yamal Y Bhagat

67. Ansuyaben J Patel

68. Ashishkumar J Patel

69. Dharmeshbhai C Patel

70. Indradaman V Shah

71. Mohammed Zaman

72. Chandubhai D Patel

73. Chandrakant C Desai

74. Anjan Shah

75. Arpita Shingala

76. Ritenkumar P Pandya

77. Ambalal Patel

78. Jayeshkumar M Patel

79. Vinubhai N Patolia

80. Gauri N Tamhane

81. Amit Shah

82. Harshadbhai P. Patel

83. Gautamumar N. Ajmeri

84. Amblal C.Patel

85. Amit R. Shahh

Further answering, see the lab notebooks and other parts of batch records of the recalled batches of Digitek® which have been produced identifying the individuals who performed testing in connection with those batches of Digitek®. See: records relating to Batch 70924 (ACTAV 000002112 – ACTAV 000003336), Batch 60236 (ACTAV 000003337 – ACTAV 000003991), Batch 60371 (ACTAV 000003992 – ACTAV 000004240), Batch 60372 (ACTAV 000004241 – ACTAV 000004969), Batch 60373 (ACTAV 000004970 – ACTAV 000005216), Batch 60319 (ACTAV 000006733 – ACTAV 000007669), Batch 60320 (ACTAV 000007670 – ACTAV 000007846), Batch 60321 (ACTAV 000007847 – ACTAV 000008141), Batch 60322 (ACTAV 000008142 – ACTAV 000008307), Batch 60323 (ACTAV 000008308 – ACTAV

000008581), Batch 60399 (ACTAV 000008582 – ACTAV 000008912), Batch 60400 (ACTAV 000008913 – ACTAV 000009153), Batch 60401 (ACTAV 000009154 – ACTAV 000009571), Batch 60402 (ACTAV 000009572 – ACTAV 000009834), Batch 60416 (ACTAV 000009835 – ACTAV 000010090), Batch 60497 (ACTAV 000010091 – ACTAV 000010249), Batch 60498 (ACTAV 000010250 – ACTAV 000010480), Batch 60499 (ACTAV 000010481 – ACTAV 000010657), Batch 60511 (ACTAV 000010658 – ACTAV 000010863), Batch 60512 (ACTAV 000010864 – ACTAV 000011041), Batch 60513 (ACTAV 0000011042 – ACTAV 000011197), Batch 60514 (ACTAV 000011198 – ACTAV 000011422), Batch 60515 (ACTAV 000011423 – ACTAV 000011585), Batch 60605 (ACTAV 000011586 – ACTAV 000011939), Batch 60606 (ACTAV 000011940 – ACTAV 000012270), Batch 60607 (ACTAV 000012271 – ACTAV 000012658), Batch 60608 (ACTAV 0000012659 – ACTAV 000012920), Batch 60643 (ACTAV 000012921 – ACTAV 000013511), Batch 60644 (ACTAV 000013512 – ACTAV 000013856), Batch 60645 (ACTAV 000013857 – ACTAV 000014119), Batch 60677 (ACTAV 000014120 – ACTAV 000014304), Batch 60678 (ACTAV 000014305 – ACTAV 000014584), Batch 60679 (ACTAV 000014585 – ACTAV 000014833), Batch 60680 (ACTAV 000014834 – ACTAV 000015021), and Batch 60681 (ACTAV 000015022 – ACTAV 000015230), Batch 60756 (ACTAV 000018757 – ACTAV 000019129), Batch 60757 (ACTA000019130 – ACTAV 000019422), Batch 60758 (ACTA000019423 – ACTAV 000019684), Batch 60759 (ACTAV 000019685 – ACTAV 000020107), Batch 60776 (ACTAV 000020108 – ACTAV 000020405), Batch 60777 (ACTAV 000020406 – ACTAV 000020667), Batch 60863, ACTAV 000020668 – ACTAV 000020907), Batch 60864 (ACTAV 000020908 – ACTAV 000021106), Batch 60865 (ACTAV 000021107 – ACTAV 000021291), Batch 60929 (ACTAV 000021292 – ACTAV 000021623), Batch 60930 (ACTAV 000021624 – ACTAV 000021922), Batch 60931 (ACTAV 000021923 – ACTAV 000022282), Batch 60932 (ACTAV 000022283 – ACTAV 000022844), Batch 60991 (ACTAV 000022845 – ACTAV 000023116); (ACTAV 000024284 – ACTAV

000024285), Batch 60992 (ACTAV 000023117 – ACTAV 000023998), Batch 60993 (ACTAV 000023999 – ACTAV 000024352), Batch 60994 (ACTAV 000024353 – ACTAV 000024634), Batch 61053 (ACTAV 000024635 – ACTAV 000024796), Batch 61054 (ACTAV 000024797 – ACTAV 000025095), Batch 61055 (ACTAV 000025096 – ACTAV 000025328), Batch 61056 (ACTAV 000025329 – ACTAV 000025494), Batch 61057 (ACTAV 000025495 – ACTAV 000025745), Batch 61092 (ACTAV 000025746 – ACTAV 000025985), Batch 61097 (ACTAV 000025986 – ACTAV 000026163), Batch 61098 (ACTAV 000026164 – ACTAV 000026402), Batch 61099 (ACTAV 000026403 – ACTAV 000026605), Batch 61100 (ACTAV 000026606 – ACTAV 000026993), Batch 61101 (ACTAV 000026994 – ACTAV 000027346), Batch 61102 (ACTAV 000027347 – ACTAV 000027639), Batch 61103 (ACTAV 000027640 – ACTAV 000027916), Batch 61104 (ACTAV 000027917 – ACTAV 000028089), Batch 70023 (ACTAV 000029372 – ACTAV 000030541), Batch 70024 (ACTAV 000030542 – ACTAV 000031026), Batch 70025 (ACTAV 000031027 – ACTAV 000031415), Batch 70026 (ACTAV 000031416 – ACTAV 000031779), Batch 70027 (ACTAV 000031780 – ACTAV 000032194), Batch 70078 (ACTAV 000032195 – ACTAV 000033348), Batch 70079 (ACTAV 000033349 – ACTAV 000033715), Batch 70080 (ACTAV 000033716 – ACTAV 000034116), Batch 70081 (ACTAV 000034117 – ACTAV 000034630), Batch 70082 (ACTAV 000034631 – ACTAV 000034995), Batch 70120 (ACTAV 000034996 – ACTAV 000035324), Batch 70121 (ACTAV 000035325 – ACTAV 000035608), Batch 70122 (ACTAV 000035609 – ACTAV 000035907), Batch 70134 (ACTAV 000035908 – ACTAV 000036297), Batch 70135 (ACTAV 000033298 – ACTAV 000036647), Batch 70136 (ACTAV 000033348 – ACTAV 000036996), Batch 70147 (ACTAV 000036997 – ACTAV 000037406), Batch 70149 (ACTAV 000037407 – ACTAV 000037696), Batch 70160 (ACTAV 000037697 – ACTAV 000038158), Batch 70161 (ACTAV 000038159 – ACTAV 000038643), Batch 70174 (ACTAV 000038644 – ACTAV 000038993), Batch 70175 (ACTAV 000038994 – ACTAV 000039349), Batch 70176 (ACTAV 000039350 – ACTAV

000039643), Batch 70207 (ACTAV 000039644 – ACTAV 000040211), Batch 70208 (ACTAV 000040212 – ACTAV 000040628), Batch 70209 (ACTAV 000040629 – ACTAV 000040982), Batch 70296 (ACTAV 000040983 – ACTAV 000041345), Batch 70297 (ACTAV 000041346 – ACTAV 000041651), Batch 70298 (ACTAV 000041652 – ACTAV 000042030), Batch 70299 (ACTAV 000042031 – ACTAV 000042335), Batch 70300 (ACTAV 000042336 – ACTAV 000042632), Batch 70370 (ACTAV 000042633 – ACTAV 000043156), Batch 70371 (ACTAV 000043157 – ACTAV 000043403), Batch 70372 (ACTAV 000043404 – ACTAV 000043803), Batch 70386 (ACTAV 000043804 – ACTAV 000044081), Batch 70454 (ACTAV 000044082 – ACTAV 000044412), Batch 70455 (ACTAV 000044413 – ACTAV 000044678), Batch 70456 (ACTAV 000044679 – ACTAV 000045023), Batch 70457 (ACTAV 000045024 – ACTAV 000045302), Batch 70458 (ACTAV 000045303 – ACTAV 000045550), Batch 70551 (ACTAV 000045551 – ACTAV 000045939), Batch 70557 (ACTAV 000045940 – ACTAV 000046291), Batch 70558 (ACTAV 000046292 – ACTAV 000046601), Batch 70559 (ACTAV 000046602 – ACTAV 000046920), Batch 70560 (ACTAV 000046921 – ACTAV 000047255), Batch 70600 (ACTAV 000047256 – ACTAV 000047653), Batch 70601 (ACTAV 000047654 – ACTAV 000048017), Batch 70664 (ACTAV 000048018 – ACTAV 000048441), Batch 70665 (ACTAV 000048441 – ACTAV 000048820), Batch 70666 (ACTAV 000048821 – ACTAV 000049097), Batch 70670 (ACTAV 000049098 – ACTAV 000049553), Batch 70671 (ACTAV 000049554 – ACTAV 00004987), Batch 70672 (ACTAV 000049874 – ACTAV 000050183), Batch 70673 (ACTAV 000050184 – ACTAV 000050544), Batch 70736 (ACTAV 000050545 – ACTAV 000051062), Batch 70737 (ACTAV 000051063 – ACTAV 000051414), Batch 70738 (ACTAV 000051415 – ACTAV 000051754), Batch 70753 (ACTAV 000051755 – ACTAV 000052161), Batch 70766 (ACTAV 000052162 – ACTAV 000052611), Batch 70767 (ACTAV 000052611 – ACTAV 000053036), Batch 70768 (ACTAV 000053037 – ACTAV 000053547), Batch 70769 (ACTAV 000053548 – ACTAV 000053976), Batch 70770 (ACTAV 000053977 – ACTAV

000054490), Batch 70811 (ACTAV 000054491 – ACTAV 000054839), Batch 70812 (ACTAV 000054840 – ACTAV 000055172), Batch 70813 (ACTAV 000055173 – ACTAV 000055535), Batch 70832 (ACTAV 000055536 – ACTAV 000055793), Batch 70833 (ACTAV 000055794 – ACTAV 000056198), Batch 70834 (ACTAV 000056199 – ACTAV 000056489), Batch 70835 (ACTAV 000056490 – ACTAV 000056780), Batch 70836 (ACTAV 000056781 – ACTAV 000057138), Batch 70925 (ACTAV 000057139 – ACTAV 000057468), Batch 70826 (ACTAV 000057469 – ACTAV 000057807), Batch 70949 (ACTAV 000057808 – ACTAV 000058172), Batch 70950 (ACTAV 000058173 – ACTAV 000058544), Batch 70951 (ACTAV 000058545 – ACTAV 000058899), Batch 70952 (ACTAV 000058900 - 000059181), Batch 70953 (ACTAV 000059182 – ACTAV 000059460), Batch 71004 (ACTAV 000059461 – ACTAV 000060005), Batch 71005 (ACTAV 000060006 – ACTAV 000060576), Batch 71032 (ACTAV 000060577 – ACTAV 000061024), Batch 71034 (ACTAV 000061025 – ACTAV 000061473), Batch 71035 (ACTAV 000061474 – ACTAV 000061945), Batch 80111 (ACTAV 000061946 – ACTAV 000062448), Batch 80191 (ACTAV 000062449 – ACTAV 000062685), Batch 80192 (ACTAV 000062686 – ACTAV 000062959). See also the ANDA for Digitek®, previously produced to Plaintiffs and identified as ACTAV 000000095 – ACTAV 000002111.

**INTERROGATORY NO. 36:**

Please list all persons including employees, managers, directors or consultants, that you have demoted, transferred, suspended, financially penalized, discharged (whether voluntary or involuntary), disciplined or laid-off, for any reason in whole or in part, in the past three years,

a) That has ever participated in the manufacturing of Digitek;

b) That has ever participated in the Regulatory, Compliance or Quality Departments functions related to Digitek.

**RESPONSE TO INTERROGATORY NO. 36:**

Defendants object to this Interrogatory on the grounds that it is overbroad and is not

reasonably calculated to lead to the discovery of admissible evidence. Responding to an interrogatory so overbroad in time and scope would be unduly burdensome for Defendants. This Interrogatory is also vague and confusing as written with respect to the undefined terms "demoted, transferred, suspended, financially penalized, discharged (whether voluntary or involuntary), disciplined or laid-off." This Interrogatory is also improper to the extent it seeks information about entities other than Defendants. Defendants further object to this Interrogatory to the extent it seeks information protected by the attorney-client privilege.

**INTERROGATORY NO. 37:**

For each person listed in the answer to the above interrogatory, please list the reason for the action taken by Actavis.

**RESPONSE TO INTERROGATORY NO. 37:**

Defendants object to this Interrogatory to the extent it is not limited to a relevant time frame or relevant persons and events, and is thus overbroad and is not reasonably calculated to lead to the discovery of admissible evidence. Responding to an interrogatory so overbroad in time and scope would be unduly burdensome for Defendants. This Interrogatory is also vague and confusing as written with respect to the undefined term and phrase "reason" and "action taken by Actavis." This Interrogatory is also improper to the extent it seeks information about entities other than Defendants. Defendants further object to this Interrogatory because it assumes foundational facts that are not in evidence. Defendants further object to this Interrogatory to the extent it seeks information protected by the attorney-client privilege.

**INTERROGATORY NO. 38:**

How were HPLC results for Digitek® calculated before the implementation of Empower?

**RESPONSE TO INTERROGATORY NO. 38:**

Defendants object to this Interrogatory to the extent it is not limited to a relevant time frame, and is thus overbroad and is not reasonably calculated to lead to the discovery of

admissible evidence. Responding to an interrogatory so overbroad in time and scope would be unduly burdensome for Defendants. This Interrogatory is also vague and confusing as written with respect to the undefined terms "calculated" and "implementation." This Interrogatory is also improper to the extent it seeks information about entities other than Defendants.

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way, and as such they join in the objections to this Interrogatory but not the substantive response.

Subject to the foregoing objections, Defendants respond as follows: Prior to implementation of Empower, HPLC results during the period of January 1, 2003 through the date of the recall of Digitek®, April 25, 2008, were calculated using Turbochrom/Totalchrom and Quattropro. In addition, a manual calculation was also performed.

**INTERROGATORY NO. 39:**

How was particle size or determined prior to implementation of "Malvern?"

**RESPONSE TO INTERROGATORY NO. 39:**

Defendants object to this Interrogatory to the extent it is not limited to information concerning Digitek®, the only product at issue in this litigation, and is not limited to a relevant time frame or relevant events, and is thus overbroad and is not reasonably calculated to lead to the discovery of admissible evidence. Responding to an interrogatory so overbroad in time and scope would be unduly burdensome for Defendants. This Interrogatory is also vague and confusing as written with respect to the undefined terms "particle size" and "implementation." This Interrogatory is also improper to the extent it seeks information about entities other than Defendants.

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way, and as such they join in the objections to this Interrogatory but not the substantive response.

Subject to the foregoing objections, Defendants respond as follows: Prior to implementation of Malvern, during the period of January 1, 2003 through the date of the recall of Digitek®, April 25, 2008, particle size was determined using Cilas Particle Size Analyzer.

**INTERROGATORY NO. 40:**

Please list the total number of Digitek® pills that were recalled.

**RESPONSE TO INTERROGATORY NO. 40:**

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way, and as such they join in the objections to this Interrogatory but not the substantive response.

Subject to the foregoing objections, Defendants respond as follows: There were 171 batches of Digitek® subject to the April 25, 2008 recall; 153 of the batches were actually released to the retail or consumer level and then recalled. See Defendants' response to Interrogatory No. 9. A theoretical batch of 0.125 mg Digitek® contains 4.8 million tablets. A theoretical batch of 0.250 mg Digitek® contains 4.2 million tablets. 83 batches of 0.125 mg Digitek®, theoretically 398,400,000 tablets, were recalled from the retail and consumer level; 70 batches of 0.25 mg Digitek®, theoretically 294,000,000 tablets, were recalled from the retail and consumer level. For precise number of tablets contained in each recalled batch, see records relating to each batch, including previously produced records relating to Batch 70924 (ACTAV 000002112 – ACTAV 000003336), Batch 60236 (ACTAV 000003337 – ACTAV 000003991), Batch 60371 (ACTAV 000003992 – ACTAV 000004240), Batch 60372 (ACTAV 000004241 – ACTAV 000004969), Batch 60373 (ACTAV 000004970 – ACTAV 000005216), Batch 60319 (ACTAV 000006733 – ACTAV 000007669), Batch 60320 (ACTAV 000007670 – ACTAV 000007846), Batch 60321 (ACTAV 000007847 – ACTAV 000008141), Batch 60322 (ACTAV 000008142 – ACTAV 000008307), Batch 60323 (ACTAV 000008308 – ACTAV 000008581), Batch 60399 (ACTAV 000008582 – ACTAV 000008912), Batch 60400 (ACTAV 000008913 –

ACTAV 000009153), Batch 60401 (ACTAV 000009154 – ACTAV 000009571), Batch 60402 (ACTAV 000009572 – ACTAV 000009834), Batch 60416 (ACTAV 000009835 – ACTAV 000010090), Batch 60497 (ACTAV 000010091 – ACTAV 000010249), Batch 60498 (ACTAV 000010250 – ACTAV 000010480), Batch 60499 (ACTAV 000010481 – ACTAV 000010657), Batch 60511 (ACTAV 000010658 – ACTAV 000010863), Batch 60512 (ACTAV 000010864 – ACTAV 000011041), Batch 60513 (ACTAV 0000011042 – ACTAV 000011197), Batch 60514 (ACTAV 000011198 – ACTAV 000011422), Batch 60515 (ACTAV 000011423 – ACTAV 000011585), Batch 60605 (ACTAV 000011586 – ACTAV 000011939), Batch 60606 (ACTAV 000011940 – ACTAV 000012270), Batch 60607 (ACTAV 000012271 – ACTAV 000012658), Batch 60608 (ACTAV 0000012659 – ACTAV 000012920), Batch 60643 (ACTAV 000012921 – ACTAV 000013511), Batch 60644 (ACTAV 000013512 – ACTAV 000013856), Batch 60645 (ACTAV 000013857 – ACTAV 000014119), Batch 60677 (ACTAV 000014120 – ACTAV 000014304), Batch 60678 (ACTAV 000014305 – ACTAV 000014584), Batch 60679 (ACTAV 000014585 – ACTAV 000014833), Batch 60680 (ACTAV 000014834 – ACTAV 000015021), and Batch 60681 (ACTAV 000015022 – ACTAV 000015230), Batch 60756 (ACTAV 000018757 – ACTAV 000019129), Batch 60757 (ACTA000019130 – ACTAV 000019422), Batch 60758 (ACTA000019423 – ACTAV 000019684), Batch 60759 (ACTAV 000019685 – ACTAV 000020107), Batch 60776 (ACTAV 000020108 – ACTAV 000020405), Batch 60777 (ACTAV 000020406 – ACTAV 000020667), Batch 60863, ACTAV 000020668 – ACTAV 000020907), Batch 60864 (ACTAV 000020908 – ACTAV 000021106), Batch 60865 (ACTAV 000021107 – ACTAV 000021291), Batch 60929 (ACTAV 000021292 – ACTAV 000021623), Batch 60930 (ACTAV 000021624 – ACTAV 000021922), Batch 60931 (ACTAV 000021923 – ACTAV 000022282), Batch 60932 (ACTAV 000022283 – ACTAV 000022844), Batch 60991 (ACTAV 000022845 – ACTAV 000023116); (ACTAV 000024284 – ACTAV 000024285), Batch 60992 (ACTAV 000023117 – ACTAV 000023998), Batch 60993 (ACTAV 000023999 –

ACTAV 000024352), Batch 60994 (ACTAV 000024353 – ACTAV 000024634), Batch 61053 (ACTAV 000024635 – ACTAV 000024796), Batch 61054 (ACTAV 000024797 – ACTAV 000025095), Batch 61055 (ACTAV 000025096 – ACTAV 000025328), Batch 61056 (ACTAV 000025329 – ACTAV 000025494), Batch 61057 (ACTAV 000025495 – ACTAV 000025745), Batch 61092 (ACTAV 000025746 – ACTAV 000025985), Batch 61097 (ACTAV 000025986 – ACTAV 000026163), Batch 61098 (ACTAV 000026164 – ACTAV 000026402), Batch 61099 (ACTAV 000026403 – ACTAV 000026605), Batch 61100 (ACTAV 000026606 – ACTAV 000026993), Batch 61101 (ACTAV 000026994 – ACTAV 000027346), Batch 61102 (ACTAV 000027347 – ACTAV 000027639), Batch 61103 (ACTAV 000027640 – ACTAV 000027916), Batch 61104 (ACTAV 000027917 – ACTAV 000028089), Batch 70023 (ACTAV 000029372 – ACTAV 000030541), Batch 70024 (ACTAV 000030542 – ACTAV 000031026), Batch 70025 (ACTAV 000031027 – ACTAV 000031415), Batch 70026 (ACTAV 000031416 – ACTAV 000031779), Batch 70027 (ACTAV 000031780 – ACTAV 000032194), Batch 70078 (ACTAV 000032195 – ACTAV 000033348), Batch 70079 (ACTAV 000033349 – ACTAV 000033715), Batch 70080 (ACTAV 000033716 – ACTAV 000034116), Batch 70081 (ACTAV 000034117 – ACTAV 000034630), Batch 70082 (ACTAV 000034631 – ACTAV 000034995), Batch 70120 (ACTAV 000034996 – ACTAV 000035324), Batch 70121 (ACTAV 000035325 – ACTAV 000035608), Batch 70122 (ACTAV 000035609 – ACTAV 000035907), Batch 70134 (ACTAV 000035908 – ACTAV 000036297), Batch 70135 (ACTAV 000033298 – ACTAV 000036647), Batch 70136 (ACTAV 000033348 – ACTAV 000036996), Batch 70147 (ACTAV 000036997 – ACTAV 000037406), Batch 70149 (ACTAV 000037407 – ACTAV 000037696), Batch 70160 (ACTAV 000037697 – ACTAV 000038158), Batch 70161 (ACTAV 000038159 – ACTAV 000038643), Batch 70174 (ACTAV 000038644 – ACTAV 000038993), Batch 70175 (ACTAV 000038994 – ACTAV 000039349), Batch 70176 (ACTAV 000039350 – ACTAV 000039643), Batch 70207 (ACTAV 000039644 – ACTAV 000040211), Batch 70208 (ACTAV 000040212 –

ACTAV 000040628), Batch 70209 (ACTAV 000040629 – ACTAV 000040982), Batch 70296 (ACTAV 000040983 – ACTAV 000041345), Batch 70297 (ACTAV 000041346 – ACTAV 000041651), Batch 70298 (ACTAV 000041652 – ACTAV 000042030), Batch 70299 (ACTAV 000042031 – ACTAV 000042335), Batch 70300 (ACTAV 000042336 – ACTAV 000042632), Batch 70370 (ACTAV 000042633 – ACTAV 000043156), Batch 70371 (ACTAV 000043157 – ACTAV 000043403), Batch 70372 (ACTAV 000043404 – ACTAV 000043803), Batch 70386 (ACTAV 000043804 – ACTAV 000044081), Batch 70454 (ACTAV 000044082 – ACTAV 000044412), Batch 70455 (ACTAV 000044413 – ACTAV 000044678), Batch 70456 (ACTAV 000044679 – ACTAV 000045023), Batch 70457 (ACTAV 000045024 – ACTAV 000045302), Batch 70458 (ACTAV 000045303 – ACTAV 000045550), Batch 70551 (ACTAV 000045551 – ACTAV 000045939), Batch 70557 (ACTAV 000045940 – ACTAV 000046291), Batch 70558 (ACTAV 000046292 – ACTAV 000046601), Batch 70559 (ACTAV 000046602 – ACTAV 000046920), Batch 70560 (ACTAV 000046921 – ACTAV 000047255), Batch 70600 (ACTAV 000047256 – ACTAV 000047653), Batch 70601 (ACTAV 000047654 – ACTAV 000048017), Batch 70664 (ACTAV 000048018 – ACTAV 000048441), Batch 70665 (ACTAV 000048441 – ACTAV 000048820), Batch 70666 (ACTAV 000048821 – ACTAV 000049097), Batch 70670 (ACTAV 000049098 – ACTAV 000049553), Batch 70671 (ACTAV 000049554 – ACTAV 00004987), Batch 70672 (ACTAV 000049874 – ACTAV 000050183), Batch 70673 (ACTAV 000050184 – ACTAV 000050544), Batch 70736 (ACTAV 000050545 – ACTAV 000051062), Batch 70737 (ACTAV 000051063 – ACTAV 000051414), Batch 70738 (ACTAV 000051415 – ACTAV 000051754), Batch 70753 (ACTAV 000051755 – ACTAV 000052161), Batch 70766 (ACTAV 000052162 – ACTAV 000052611), Batch 70767 (ACTAV 000052611 – ACTAV 000053036), Batch 70768 (ACTAV 000053037 – ACTAV 000053547), Batch 70769 (ACTAV 000053548 – ACTAV 000053976), Batch 70770 (ACTAV 000053977 – ACTAV 000054490), Batch 70811 (ACTAV 000054491 – ACTAV 000054839), Batch 70812 (ACTAV 000054840 –

ACTAV 000055172), Batch 70813 (ACTAV 000055173 – ACTAV 000055535), Batch 70832 (ACTAV 000055536 – ACTAV 000055793), Batch 70833 (ACTAV 000055794 – ACTAV 000056198), Batch 70834 (ACTAV 000056199 – ACTAV 000056489), Batch 70835 (ACTAV 000056490 – ACTAV 000056780), Batch 70836 (ACTAV 000056781 – ACTAV 000057138), Batch 70925 (ACTAV 000057139 – ACTAV 000057468), Batch 70826 (ACTAV 000057469 – ACTAV 000057807), Batch 70949 (ACTAV 000057808 – ACTAV 000058172), Batch 70950 (ACTAV 000058173 – ACTAV 000058544), Batch 70951 (ACTAV 000058545 – ACTAV 000058899), Batch 70952 (ACTAV 000058900 - 000059181), Batch 70953 (ACTAV 000059182 – ACTAV 000059460), Batch 71004 (ACTAV 000059461 – ACTAV 000060005), Batch 71005 (ACTAV 000060006 – ACTAV 000060576), Batch 71032 (ACTAV 000060577 – ACTAV 000061024), Batch 71034 (ACTAV 000061025 – ACTAV 000061473), Batch 71035 (ACTAV 000061474 – ACTAV 000061945), Batch 80111 (ACTAV 000061946 – ACTAV 000062448), Batch 80191 (ACTAV 000062449 – ACTAV 000062685), Batch 80192 (ACTAV 000062686 – ACTAV 000062959). See also the ANDA for Digitek®, previously produced to Plaintiffs and identified as ACTAV 000000095 – ACTAV 000002111.

**INTERROGATORY NO. 41:**

For each recalled batch, please list the distributor.

**RESPONSE TO INTERROGATORY NO. 41:**

Defendants object to this Interrogatory because it is improper to the extent it seeks information about entities other than Defendants.

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way, and as such they join in the objections to this Interrogatory but not the substantive response.

Subject to the foregoing objections, Defendants respond as follows: Each batch of recalled Digitek® was distributed by Mylan Pharmaceuticals, Inc., Mylan Bertek

Pharmaceuticals, or UDL Laboratories, Inc.

**INTERROGATORY NO. 42:**

Please list the total number of prescriptions covered by the recall.

**RESPONSE TO INTERROGATORY NO. 42:**

Defendants object to this Interrogatory because it is improper to the extent it seeks information about entities other than Defendants.

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way, and as such they join in the objections to this Interrogatory but not the substantive response.

Subject to the foregoing objections, Defendants respond as follows: Defendants do not possess any information that is responsive to this Interrogatory.

**INTERROGATORY NO. 43:**

Please describe how you track the distribution of Digitek® from the time the batch leaves Actavis until it reaches a consumer.

**RESPONSE TO INTERROGATORY NO. 43:**

Defendants object to this Interrogatory to the extent it is not limited to a relevant time frame or relevant events, and is thus overbroad and is not reasonably calculated to lead to the discovery of admissible evidence. Responding to an interrogatory so overbroad in time and scope would be unduly burdensome for Defendants. This Interrogatory is also vague and confusing as written with respect to the undefined term and phrase "track" and "leaves Actavis." This Interrogatory is also improper to the extent it seeks information about entities other than Defendants.

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way, and as such they join in the objections to this Interrogatory but not the substantive response.

Subject to the foregoing objections, Defendants respond as follows: Actavis distributes all Digitek® to Mylan Pharmaceuticals, Inc. and tracks distribution to Mylan Pharmaceuticals through sales and shipping documents reflecting and relating to Mylan's purchase of Digitek®. Actavis does not track distribution of Digitek® beyond Mylan to either the retail or consumer level.

**INTERROGATORY NO. 44:**

Please describe how you tracked pills once they were returned due to the recall including return to your custody, Mylan's custody, a pharmacy, a doctor or stericycle.

**RESPONSE TO INTERROGATORY NO. 44:**

Defendants object to this Interrogatory to the extent it is not limited to a relevant time frame or relevant events, and is thus overbroad and is not reasonably calculated to lead to the discovery of admissible evidence. Responding to an interrogatory so overbroad in time and scope would be unduly burdensome for Defendants. This Interrogatory is also vague and confusing as written with respect to the undefined term "tracked." This Interrogatory is also improper to the extent it seeks information about entities other than Defendants. Defendants further object to this Interrogatory because it assumes foundational facts that are not in evidence. Defendants further object to this Interrogatory to the extent it seeks information protected by the attorney-client privilege.

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way, and as such they join in the objections to this Interrogatory but not the substantive response.

Subject to the foregoing objections, Defendants respond as follows: No Digitek® tablets have been returned to Actavis due to the recall. Pursuant to the Digitek® recall notice, Digitek® returned due to the recall is returned to Stericycle, the third-party vendor hired by Mylan to coordinate the recall and receive all returned product. Actavis does not track any Digitek®

returned due to the recall.

**INTERROGATORY NO. 45:**

Referring you to page 11 of the ANDA Annual Report dated 2/21/05 covering the period of 1/1/2004 – 12/31/2004, produced as Bates ACTA000005697, where it states "thick tablet"… "tablet was left in vibrator during the set up of the machine and passed undetected," please provide a detailed description of each and every fact relating to this referred to Adverse Event / AER, including but not limited to:

a) the date that you received or gained knowledge of this Adverse Event / AER;

b) how you gained knowledge of this Adverse Event / AER;

c) who received the information about this Adverse Event / AER;

d) the identity of the person or persons who reported any information about this Adverse Event / AER;

e) the identity of the person or persons with the most knowledge about this Adverse Event / AER;

f) each and every action you took in response to receiving or gaining knowledge of this Adverse Event / AER, including investigating it and reporting it to the FDA (including the date you reported it, if you did so);

g) any actions or measure you took to address or remedy this Adverse Event / AER;

h) identify all persons who on your behalf, whether an employee, consultant, or other person was involved with addressing, remedying or taking any action regarding this Adverse Event / AER;

i) identify each and every document related, generated from, exchanged between you and the FDA, relating to this Adverse Event / AER;

j) identify any of your employees, managers, officers, directors, or consultants disciplined, reprimanded, given a written or verbal warning, terminated / fired /

discharged, suspended voluntarily or involuntarily laid off or retired, in any way as a result of the Adverse Event / AER.

**RESPONSE TO INTERROGATORY NO. 45:**

Defendants object to this Interrogatory to the extent it is not limited to a relevant time frame or relevant persons and events, and is thus overbroad and is not reasonably calculated to lead to the discovery of admissible evidence. Responding to an interrogatory so overbroad in time and scope would be unduly burdensome for Defendants. The inclusion of the phrase "including but not limited to…" also makes this Interrogatory overbroad. This Interrogatory is also vague and confusing as written with respect to the undefined terms and phrases "received or gained knowledge" and "disciplined, reprimanded, given a written or verbal warning, terminated / fired / discharged, suspended voluntarily or involuntarily laid off or retired, in any way as a result." Defendants also object on the grounds that the requested information may infringe upon the privacy interests of patients or physicians or violate federal or state privacy laws or regulations, including 21 C.F.R. § 20.63(f). This Interrogatory is also improper to the extent it seeks information about entities other than Defendants.

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way, and as such they join in the objections to this Interrogatory but not the substantive response.

Subject to the foregoing objections, Defendants respond as follows: See Defendants' responses to Interrogatory, No. 6, and to Requests for Production of Documents, Nos. 24, 25, 26, and 27.

**INTERROGATORY NO. 46:**

With regard to the tightened AGQL inspection and the AQL Sample Plan or Investigation 07-093 for Lot 70924A1, please state the following:

a) whether the FDA was advised, consulted or notified about the AQL inspection and/or

the AQL Sample Plan before both were implemented, and if so, when and who was in contact with the FDA;

b) whether the FDA approved the AQL inspection and/or the AQL Sample Plan before both were implemented;

c) identify the person or persons at the FDA who had knowledge of the AQL inspection and/or the AQL Sample Plan prior to implementation by you;

d) identify each person or person involved how the AQL inspection and AQL Sample Plan were to be conducted / implemented;

e) identify each person or persons involved with defining the parameters of the AQL Sample Plan was;

f) identify any standard, regulation, protocol, procedure, or methodology that you used to develop and define the AQL Sample plan;

g) state each and every reason why as part of the AQL Sample Plan you selected 1250 tablets as the minimum number of tables to inspect;

h) state each and every reason why as part of the AWL Sample Plan you decided to "Accept on 1 / Reject on 2 (total for batch) as stated on ACTAV 000002615;

i) identify any standard, regulation, protocol, procedure, or methodology, that you relied on when, as part of the AQL Sample Plan, you decided to "Accept on 1 / Reject on 2 (total for batch) as stated on ACTAV 000002615;

j) how many of the 4,747,428 (4,800,000 Theoretical) tablets you inspected;

k) identify any and all equipment utilized during the AQL inspection and AQL Sample Plan to inspect the tablets;

l) state the inspection criterion used by you during the tightened AQL inspection and the AQL Sample Plan; and

m) identify each and every person that inspected tablets during the tightened AQL

inspection and the AQL Sample Plan.

**RESPONSE TO INTERROGATORY NO. 46:**

Defendants object to this Interrogatory to the extent it is not limited to a relevant time frame or relevant persons and events, and is thus overbroad and is not reasonably calculated to lead to the discovery of admissible evidence. Responding to an interrogatory so overbroad in time and scope would be unduly burdensome for Defendants. This Interrogatory is also vague and confusing as written with respect to the undefined terms and phrases "tightened," "implemented," "implementation," "defining the parameters," "standard, regulation, protocol, procedure, or methodology that you used to develop and define," and **"**inspection criterion used by you." This Interrogatory is also improper to the extent it seeks information about entities other than Defendants.

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way, and as such they join in the objections to this Interrogatory but not the substantive response.

Subject to the foregoing objections, Defendants respond as follows:

a) No.

b) No.

c) See response to a) above.

d) Defendants cannot respond to this subsection because it is unintelligible as written. See documents previously produced as ACTAV 000002576 – ACTAV 000002643.

e) Dan Bitler and Scott Talbot. See documents previously produced as ACTAV 000002576 – ACTAV 000002643.

f) MIL–STD–105E.

g) The minimum number of tablets to sample is prescribed by MIL–STD–105E for a Tightened AQL Level 1 inspection.

h) The acceptance criteria are prescribed by MIL–STD–105E for a Tightened AQL Level 1 inspection.

i) MIL–STD–105E.

j) Every one of the 4,747,428 tablets in Batch 70924A was visually inspected.

k) At the time of the Tightened AQL Inspection, the tablets from Batch 70924A were being held in 33 full buckets and a partially full 34th bucket. The appropriate numbers of random sample tablets were removed from different locations of each bucket using a scoop and then were inspected.

l) See documents previously produced as ACTAV 000002576 – ACTAV 000002643.

m) See documents previously produced as ACTAV 000002576 – ACTAV 000002643.

Dated: July 24, 2009

TUCKER ELLIS & WEST LLP

By: */s/ Richard A. Dean*

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**CERTIFICATE OF SERVICE**

A copy of Defendants Actavis Totowa LLC, Actavis Inc., and Actavis Elizabeth LLC's Responses to Plaintiffs' Second Set of Interrogatories was sent via electronic mail this 24th day of July, 2009 to:

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